Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0668399	01/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Haydel Medical Clinic	502 Barrow, Houma, 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 on January 11, 2023 through January 12, 2023 at Haydel Medical Clinic, CLIA ID # 19D0668399. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with personnel, the laboratory failed to retain QC records associated with range changes for Chemistry testing for at least two (2) years. Findings: 1. In interview on January 11, 2023 at 10: 24 am, the Technical Consultant stated the laboratory no longer performs Vitamin D testing. 2. Review of the laboratory's quality control records for Chemistry for July 2021, August 2022, and November 2022 revealed Vitamin D had unacceptable QC documented for July 16, 2021 and July 21, 2021. 3. In interview on January 11, 2023 at 11:23 am the Technical Consultant stated there was an update from the manufacturer for the quality control ranges for Vitamin D; however, she did not maintain the QC records that included the new ranges and date put into use. The Technical Consultant stated on July 16, 2021 eight (8) patients and July 21, 2021 two (2) patients were reported.
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: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish complete written policies and procedures to assess competency of laboratory personnel. Findings: 1. Review of the laboratory's "Personnel assessments" policy revealed the laboratory did not include a written policy that included 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. Further review of the laboratory's "Personnel assessments" policy revealed the laboratory did not include a written procedure that included, but not limited to, monitors assessed and frequency of performance for the competency assessment for personnel serving as Technical Consultant. 3. In interview on January 11, 2023 at 11:21 am, the Technical Consultant confirmed the laboratory's policies did not include the identified information.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency testing (PT) records, and interview with personnel the laboratory failed to ensure complete documentation of review of PT results. Findings: 1. Review of the laboratory's "Proficiency testing (PT) policy revealed "PT will be reviewed by the technical supervisor, the lab director, and the lab staff at different intervals but no less than described on the Quality Assessment calendar." 2. Review of the laboratory's PT records for 2021 and 2022 revealed an "Investigation of Unacceptable Results" document was used for assessment of unacceptable Lymphocytes % (Sample SXT-15) and Helicobacter pylori (sample HP-6) results for 2022 Testing Event 3. 3. Further review of the "Investigation of Unacceptable Results" document revealed the laboratory did not complete /include the following information listed on their forms: a) "Survey Event, PT Provider, Date Testing Performed": the information was documented b) "Laboratory Director Review": Laboratory Director did not sign indicating his review; however "11/15/22" was indicated on the date line 4. In interview on January 12, 2023 at 5:00 pm, the Technical Consultant confirmed the identified information and Laboratory Director's review were not included.
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 interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written policies and procedures that included the following: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, and actions to take when data from the studies fail to meet acceptability criteria b) Detailed Complete Blood Count (CBC) flag policy that included a complete list of instrument flags c) Updated SARS COV-2 reporting policy that includes what is reported to state agency d) Proficiency testing: to include, but not limited to, what is assessed and form utilized for documentation of assessment 2. In interview on January 11, 2023 at 12:08 pm, the Technical Consultant confirmed the laboratory did not include the identified polices and procedures.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of policies and interview with personnel, the laboratory failed to document the dates of discontinuance for tests no longer performed. Findings: 1. Review of the laboratory's "Analytic phase" policy under the "Procedure manual" section revealed "Discontinued procedures are retained for two years and the discontinued date is noted." 2. Review of the laboratory's policies and procedures revealed procedures related to Vitamin D, Vitamin B-12 testing, Helicobacter (H.) pylori (waived) testing. 3. In interview on January 11, 2023 at 10:24 am, the Technical Consultant stated the laboratory no longer performs Vitamin D testing. 4. In interview on January 11, 2023 at 11:08 am, the Technical Consultant stated the laboratory discontinued the Aim Step H. pylori test. 5. In further interview on January 11, 2023 at 1:11 pm. the Technical Consultant stated the laboratory no longer performs Vitamin D and Vitamin B-12 testing as of September 2021. 6. Further review of the laboratory's policies and procedures revealed the laboratory did not include the date of discontinuance for the identified tests.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on observation by surveyors, review of manufacturers' requirements, and interview with personnel, the laboratory failed to monitor the temperature where sample collection supplies were stored per manufacturer requirements. Findings: 1. Observation by surveyors during the laboratory tour on January 11, 2023 at 10:04 am revealed the following items stored in the phlebotomy area without temperature monitoring: a) BD Vacutainer K2EDTA blood collection tubes, Lot 2227125, Quantity: three (3) packs b) BD Vacutainer SST blood collection tubes, Lot 2291711, Quantity: three (3) packs c) 100 esr vacuum tubes, Lot 12010851, Quantity: one (1) box d) BD Vacutainer serum blood collection tubes, Lot 2161937, Quantity: fifteen (15) tubes e) BD Vacutainer serum blood collection tubes, Lot 1349713, Quantity: eight (8) tubes f) Fisherbrand Microorganism Collection and Transport Tubes, Lot 2G11A, Quantity: seven (7) tubes 2. Review of the manufacturers' storage requirements for the identified sample collection supplies revealed the following: a) BD Vacutainer K2EDTA blood collection tubes: storage requirement 4-25 degrees Celsius b) BD Vacutainer SST blood collection tubes: storage requirement 4-25 degrees Celsius c) 100 esr vacuum tubes: storage requirement 2-30 degrees Celsius d) BD Vacutainer serum blood collection tubes: storage requirement 4-25 degrees Celsius e) Fisherbrand Microorganism Collection and Transport Tubes: storage requirement 4-25 degrees Celsius 3. In interview on January 11, 2023 at 10:15 am, the Technical Consultant stated the temperature is not monitored in the phlebotomy area.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, and interview with personnel, the laboratory failed to ensure supplies and reagents did not exceed their expiration dates. Findings: 1. Observation by surveyors during the laboratory tour on January 11, 2023 at 10:04 am revealed the following expired items: a) Hologic Aptima Urine Specimen Transport Tubes, Lot 284808, Expiration Date: 11-30-21, Quantity: fourteen (14) tubes b) BD Vacutainer SST blood collection tubes, Lot 0275632, Expiration Date: 2021-09-30, Quantity: one (1) tube c) BD Vacutainer KEDTA, Lot 1014105, Expiration Date: 2022-05-31, Quantity: one (1) tube d) FP Cal, Lot 54164101, Expiration Date: 2022-12-31, Quantity: one (1) pack e) Elecsys SysWash, Lot 54639801, Expiration Date: 2022-07-31, Quantity: one (1) bottle f) Elecsys Vitamin B12 11, Lot 54148101, Expiration Date: 2022-12-31, Quantity: one (1) box 2. Review of the laboratory's policies under the "Test systems, equipment, instruments, reagents, materials, and supplies" section revealed "Reagents, materials, and supplies are not used beyond expiration dates." 3. In interview on January 11, 2023 at 10:37 am, the Technical Consultant confirmed the identified items were expired.
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: I. Based on observation by surveyors, review of policies, review of performance specification studies, and interview with personnel, the laboratory failed to ensure complete verification of performance specification studies for Chemistry testing. Findings: 1. Observation by surveyors during the laboratory tour on January 11, 2023 at 10:04 am revealed the laboratory utilizes the following instruments for Chemistry testing: Cobas Integra 400 plus Cobas e411 2. In interview on January 11, 2023 at 1: 30 pm, the Technical Consultant stated after Hurricane Ida the laboratory re-validated the Chemistry and Hematology analyzers in June 2022 by performing a full validation as if new instruments. 3. Review of the laboratory's performance specification (validation) studies revealed the following information was not included: a) Acceptability criteria for correlations b) Accuracy performed over the course of ten (10) days as stated in summary c) Precision studies to include, day to day over the course of ten (10) days as stated in summary d) Reportable ranges in summary chart did not match the raw data 4. In further interview on January 11, 2023 at 1:30 pm, the Technical Consultant confirmed the identified information was not included in the laboratory's performance verification studies of the Chemistry analyzers. II. Based on observation by surveyors, review of policies, review of performance specification studies, and interview with personnel, the laboratory failed to ensure complete verification of performance specification studies for Hematology testing. Findings 1. Observation by surveyors during the laboratory tour on January 11, 2023 at 10:04 am revealed the laboratory utilizes the Sysmex XN 430 for Hematology testing. 2. In interview on January 11, 2023 at 1:30 pm, the Technical Consultant stated after Hurricane Ida the laboratory re-validated the Chemistry and Hematology analyzers in June 2022 by performing a full validation as if new instruments. 3. Review of the laboratory's performance specification (validation) studies revealed the following information was not included: a) Acceptability criteria for correlations b) Accuracy performed over the course of ten (10) days as stated in summary c) Precision studies to include, day to day over the course of ten (10) days as stated in summary d) Reportable ranges in summary chart did not match the raw data 4. In further interview on January 11, 2023 at 1:30 pm, the Technical Consultant confirmed the identified information was not included in the laboratory's performance verification studies of the Hematology analyzer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on observation by surveyors, review of maintenance logs, policies, and

interview with personnel, the laboratory failed to ensure maintenance was performed as required for the Cobas e411 analyzer as required for two (2) of seven (7) months reviewed in 2022. Findings: 1. Observation by surveyors during the laboratory tour on January 11, 2023 at 10:04 am revealed the laboratory utilizes the following Chemistry analyzers: Cobas Integra 400 plus Cobas e411 2. In interview on January 11, 2023 at 9:39 am, the Technical Consultant stated the laboratory was closed September 1, 2021 through middle of June 2022 due to Hurricane Ida. 3. Review of the laboratory's "Maintenance and function Checks" policy revealed "A review of maintenance checks will be done at least annually. The review will include" All maintenance follows manufacturer instructions, all maintenance (daily, weekly, biweekly, monthly) is performed and documented, and all function checks are within manufactures {sic} limits before patient testing begins." 4. Review of the Cobas e411 maintenance logs revealed the following tasks: a) Weekly: Clean incubator and aspiration station Clean sipper probe b) Every two (2) weeks: Clean rinse stations Perform liquid flow cleaning 5. Further review of the laboratory's maintenance logs for the Cobas e411 from June 2022 through December 2022 revealed the following maintenance was not documented as required: a) September 2022: Weekly: missing for the week of September 5, 2022 and September 26, 2022 Every two (2) weeks: missing for the week of September 26, 2022 b) November 2022: Weekly: missing for the week of November 28, 2022 Every two (2) weeks: missing for the weeks of November 14, 2022 and November 28, 2022 6. In interview on January 12, 2023 at 12:26 pm, the Technical Consultant stated maintenance is documented on the maintenance logs and if it is not documented there then it was not performed. II. Based on observation by surveyors, review of maintenance logs, and interview with personnel, the laboratory failed to ensure maintenance was performed as required for the Cobas Integra 400 plus analyzer as required for nine (9) of fifteen (15) months reviewed. Findings: 1. Observation by surveyors during the laboratory tour on January 11, 2023 at 10:04 am revealed the laboratory utilizes the following Chemistry analyzers: Cobas Integra 400 plus Cobas e411 2. In interview on January 11, 2023 at 9:39 am, the Technical Consultant stated the laboratory was closed September 1, 2021 through middle of June 2022 due to Hurricane Ida. 3. Review of the laboratory's "Maintenance and function Checks" policy revealed "A review of maintenance checks will be done at least annually. The review will include" All maintenance follows manufacturer instructions, all maintenance (daily, weekly, biweekly, monthly) is performed and documented, and all function checks are within manufactures {sic} limits before patient testing begins." 4. Review of the Cobas Integra 400 plus maintenance logs revealed the following tasks: a) Weekly: Clean probes and splash guard Clean ISE tower automatically Back up database b) Monthly: Clean waste box fitting Clean ISE tower manually c) Quarterly: Replace ventilation filters Replace external water reservoir filter d) Semi-annual: Clean external water reservoir Clean fluid water reservoir Clean internal water reservoir Clean wash station Replace ISE tubing e) Electrode replacement frequency: Chloride electrode every 90 days Lithium electrode every 120 days Sodium electrode every 180 days Potassium electrode every 180 days Reference electrode every 720 days 5. Further review of the laboratory's maintenance logs for the Cobas Integra 400 plus revealed the following maintenance was not documented as required for 2021 and 2022: a) January 2021: Chloride electrode replacement due b) March 2021: Weekly: missing for the week of March 22, 2021 c) May 2021: Weekly: missing for the week of May 3, 2021 d) July 2021: Chloride electrode replacement due e) August 2021: Monthly: Clean ISE tower manually f) August 2022: Weekly: missing for the week of August 15, 2022 g) September 2022: Weekly: missing for the week of September 19, 2022 Quarterly due Chloride electrode replacement due (performed November 10, 2022) h) November 2022: Monthly: Clean ISE tower manually i) December 2022: Semi-annual due 6. In

	interview on January 12, 2023 at 12:26 pm, the Technical Consultant stated maintenance is documented on the maintenance logs and if it is not documented there then it was not performed. III. Based on observation by surveyors, review of maintenance logs, and interview with personnel, the laboratory failed to ensure maintenance was performed as required for the Sysmex XN-430 analyzer as required for three (3) of fifteen (15) months reviewed. Findings: 1. Observation by surveyors during the laboratory tour on January 11, 2023 at 10:04 am revealed the laboratory utilizes the Sysmex XN-430 for Complete Blood Count (CBC) testing. 2. In interview on January 11, 2023 at 9:39 am, the Technical Consultant stated the laboratory was closed September 1, 2021 through middle of June 2022 due to Hurricane Ida. 3. Review of the laboratory's XN-430 Maintenance logs revealed the following maintenance tasks: a) Weekly: routine cleaning 4. Further review of the laboratory's maintenance logs for the Sysmex XN-430 revealed the following maintenance was not documented as required for 2021 and 2022: a) November 2021: Weekly: missing for the week of November 22, 2021 b) December 2021: Weekly: missing for the week of December 27, 2021 c) April 2022: Weekly: missing for the week of April 11, 2022 d) May 2022: Weekly missing for the week of May 23, 2022 e) November 2022: Weekly: missing for the week of November 21, 2022 5. In interview on January 12, 2023 at 12:26 pm, the Technical Consultant stated maintenance is documented on the maintenance logs and if it is not documented there then it was not performed.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) policies and interview with personnel, the laboratory failed to establish complete QC policies for Chemistry and Hematology testing. Findings: 1. Review of the laboratory's "Quality Control Policy" revealed "The mean target value of a new lot of quality control material will be calculated by evaluating at least 20 days of quality control results run in parallel with the current quality control lot. Values for standard deviation and coefficient of variation are calculated and a Levy-Jennings plot is created. Daily QC results are plotted on this chart." 2. Further review of the laboratory's "Quality Control Policy" under the "Procedure For Out of Range Quality Control Results" revealed the laboratory did not include when to perform patient assessment. 3. Further review of the laboratory's policies under "New Lots" section revealed "New lots of controls will be run 5 times to verify the manufacturer mean and standard deviation," which differed from the "Quality Control Policy." 4. In interview on January 11, 2023 at 9: 55 am, the Technical Consultant stated prior to use of a new lot on controls for Chemistry testing the controls are run five (5) times and the means are compared to that of the manufacturer's. The Technical Consultant further stated prior to use of a

	new lot of controls for Hematology testing the controls are run ten (10) times to verify the manufacturer's. The Technical Consultant confirmed the laboratory's QC policies did not match what was in practice.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, quality control records, quality assessment of quality control records, and interview with personnel, the laboratory failed to document corrective actions performed for quality control reruns. Findings: 1. Review of the laboratory's "QC management" policy revealed "QC is evaluated daily. QC is printed daily and/or weekly and monthly." 2. Review of the laboratory's "Quality Control Review" revealed "Controls are monitored daily to ensure accuracy and precision. Yearly, the quality control monitor will be used to generate a score to compare to the threshold value. If the score does not meet the threshold value corrective action must be taken and documented. A reevaluation will occur in 30 days to determine the effectiveness of the corrective action." 3. Review of the laboratory's quality control and quality assessment records for Complete Blood Count (CBC) for August 2022 and November 2022 revealed the laboratory performed the following quality controls multiple times without documentation detailing the reason: August 10, 2022: Level 1 ran three (3) times August 17, 2022: Level 2 ran twice and Level 3 ran seven (7) times August 22, 2022: Level 1 ran four (4) times, Level 2 ran twice, and Level 3 ran twice August 26, 2022: Level 1 ran eight (8) times, Level 2 ran four times, and Level 3 ran six (6) times November 14, 2022: Level 1 ran five (5) times, Level 2 ran three (3) times, and Level 3 ran twice November 16, 2022: Level 1 ran three (3) times and Level 3 ran twice November 18, 2022: Level 1 ran three (3) times and Level 2 ran twice November 30, 2022: Level 1 ran three (3) times and Level 2 ran three (3) times and Level 3 ran five (5) times 4. In interview on January 12, 2023 at 3: 30 pm, the Technical Consultant stated she did know why there were multiple runs of quality control on the identified dates.
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 surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Findings: 1. The laboratory failed to ensure complete verification of performance specification studies for Chemistry testing. Refer to D5421 I. 2. The laboratory failed to ensure complete verification of performance specification studies for Hematology testing. Refer to D5421 II.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to monitor the temperature where sample collection supplies were stored per manufacturer requirements. Refer to D5413. 2. The laboratory failed to ensure supplies and reagents did not exceed their expiration dates. Refer to D5417.
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 record review and interview with personnel, the Laboratory Director failed to ensure proficiency testing evaluation forms were completed. Refer to D5221.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels

	of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to ensure maintenance was performed as required for the Cobas e411 analyzer as required for two (2) of seven (7) months reviewed in 2022. Refer to D5429 I. 2. The laboratory failed to ensure maintenance was performed as required for the Cobas Integra 400 plus analyzer as required for nine (9) of fifteen (15) months reviewed. Refer to D5429 II. 3. The laboratory failed to ensure maintenance was performed as required for the Sysmex XN-430 analyzer as required for three (3) of fifteen (15) months reviewed. Refer to D5429 III.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were documented when deviations from laboratory's policies occurred. Refer to D5781.
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 review of the laboratory's policies, personnel records, and interview with personnel, the Laboratory Director failed to evaluate the competency annually for 2022 for one (1) of one (1) current Testing Personnel for Chemistry testing. Findings: 1. Review of the laboratory's "Personnel assessments" policy revealed "Personnel assessments will be done annually by the laboratory director and/or the technical supervisor..." 2. Review of personnel records for the Technical Consultant (who also

	serves as Testing Personnel 1) revealed an annual competency assessment in 2022 was not performed for the Cobas instruments (Cobas Integra 400 plus and Cobas e411). 3. In interview on January 11, 2023 at 11:21 am, the Technical Consultant stated the Cobas instrument was not operational in January 2022 at the time of competency performance; however, was not completed later that year when put back into use. II. Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
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 establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to document the dates of discontinuance for tests no longer performed. . Refer to D5409.
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 policies, personnel records, and interview with personnel, the Laboratory Director failed to provide written job responsibilities for laboratory personnel. Findings: 1. Review of the laboratory's policies and personnel records revealed the laboratory did not include written job responsibilities for the following personnel: Laboratory Director Clinical Consultant Technical Consultant Testing Personnel 2. In interview on January 11, 2023 at 11:21 am, the Technical Consultant confirmed the laboratory did not include written job responsibilities for the identified laboratory personnel.
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 surveyors, 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 retain QC records associated with range changes for Chemistry testing for at least two (2) years. Refer to D3031. 2. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 3. The laboratory failed to document the dates of discontinuance for tests no longer performed. Refer to D5409. 4. The laboratory failed to monitor the temperature where sample collection supplies were stored per manufacturer requirements. Refer to D5413. 5. The laboratory failed to ensure supplies and reagents did not exceed their expiration dates. Refer to D5417. 6. The laboratory failed to ensure maintenance was performed as required for the Cobas e411 analyzer as required for two (2) of seven (7) months reviewed in 2022. Refer to D5429 I. 7. The laboratory failed to ensure maintenance was performed as required for the Cobas Integra 400 plus analyzer as required for nine (9) of fifteen (15) months reviewed. Refer to D5429 II. 8. The laboratory failed to ensure maintenance was performed as required for the Sysmex XN-430 analyzer as required for three (3) of fifteen (15) months reviewed. Refer to D5429 III.
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 surveyors, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Findings: 1. The laboratory failed to ensure complete verification of performance specification studies for Chemistry testing. Refer to D5421 I. 2. The laboratory failed to ensure complete verification of performance specification studies for Hematology testing. Refer to D5421 II.
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. Findings: 1. The laboratory failed to retain QC records associated with range changes for Chemistry testing for at least two (2) years. Refer to D3031. 2. The laboratory failed to establish complete QC policies for Chemistry and Hematology testing. Refer to D5441.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were documented when deviations form the laboratory's policies occurred. Refer to D5781.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, and interview with personnel, the Technical Consultant failed to perform the semi-annual assessment of one (1) of two (2) previously employed testing personnel. Findings: 1. Review of the laboratory's "Personnel assessments" policy revealed "Documentation of competency after first six months of employment and the {sic} annually there after." 2. Review of the laboratory's personnel records revealed Testing Personnel 2 was no longer employed as of August 2022; however, the initial training was performed in October 2021. 3. Further review of personnel records for Testing Personnel 2 revealed the laboratory documented a competency assessment performed January 27, 2022. The semi-annual competency for Testing Personnel 2 would have been due April 2022. 4. In interview on January 11, 2023 at 11:21 am the Technical Consultant stated competency assessments for laboratory personnel are performed in January.