Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2227002	02/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Tate County Hospital Dba Highland Hills Medical Ct	401 Getwell Dr, Senatobia, MS	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) events and interview with the laboratory manager/GS as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to retain proficiency test records for Hematology and Chemistry for two of five PT events. Findings include: 1. Review of the Hematology proficiency testing records for Events 2 and 3 of 2022 and Events 1, 2, and 3 of 2023 revealed the laboratory failed to retain the Hematology attestation statement and analyzer printouts for Event 1 of 2023(1 of 5 events). 2. Review of the Chemistry proficiency testing records for Events 2 and 3 of 2022 and Events 1, 2 and 3 of 2023 revealed the laboratory failed to retain the Core Chemistry attestation statements and analyzer printouts for Events 1 and 2 of 2023(2 of 5 events). 3. In an interview on 2/7/2024 at 2:30 p.m., the laboratory manager/GS confirmed Hematology analyzer printouts and attestation statement for Event 1 and Core Chemistry attestation statement and analyzer printouts for event 1 and event 2 were unavailable the day of survey.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, lack of verification of

	accuracy, and interview with the general supervisor (GS) listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to verify the accuracy, at least twice annually, for Reticulocyte Count (retic count) and HIV-1 p24 testing for 2 of 4 verifications. Findings included: 1. Review of proficiency testing records and lack of verification records for retic count and HIV-1 p24 revealed no twice annual test verification was performed for 2 of 4 verifications due for the year 2022. 2. During an interview with the GS on 2/7/2023 at 3:00 p.m. it was confirmed no twice annual test verifications for retic count and HIV-1 p24 were performed for the year 2022.
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 the number of deficiencies cited for analytic systems, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 492.1283 or monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289. Refer to D5447- (Failure to perform 2 levels of quantitative QC each day of patient testing.) Refer to D5449- (Failure to perform 2 levels of qualitative QC each day of patient testing.) Refer to D5479 - (Failure to report QC in the same measurement/reaction as patients are reported.) Refer to D5551 -(Failure to perform QC each day of blood bank testing.)
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the MiniSed Automated sedimentation rate (ESR) quality control (QC) log, patient test log and interview with the laboratory manager/GS as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the testing personnel failed to include at least two levels of quality control each day of patient testing. Approximately 10 patients were reported on 9 of 85 days of testing ESR when no QC was performed. Findings Include: 1. According to the MiniSed Automated ESR QC and patient logs 6/4/2022 through 8/30/2022 revealed QC was not documented as performed each day when patients for ESR were tested and reported. 2. A review and comparison between the ESR QC logs and the patient logs revealed on the following days an ESR test was performed on patients' specimens and no QC was documented as tested on 9 of 85 days: 6/04/2022 - 1 patient result reported

	6/20/2022 - 1 patient result reported 6/28/2022 - 2 patient results reported 7/01/2022 - 1 patient result reported 7/05/2022 - 1 patient result reported 8/14/2022 - 1 patient result reported 8/16/2022 - 1 patient result reported 8/17/2022 - 1 patient result reported 8/26/2022 - 1 patient result reported 3. In an interview, the lab manager/GS confirmed on 2/7/2024 at 11:30 a.m, two levels of QC were not performed when ESR was tested on patients using the MiniSed ESR automated analyzer and results reported on the above mentioned days.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of an IQCP (Individualized Quality Control Plan), a review of quality control (QC) records for Abbott HIV 1/2 Ag/Ab Combo test kit and interview with the lab manager/general supervisor (GS) as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to document a positive and negative control on each day of patient testing for 15 of 15 days when the HIV 1/2 Ag/Ab Combo kit was used. Findings Include: 1. There was no IQCP (Individualized Quality Control Plan) available for review on the day of survey. An IQCP is required if two levels of quality control (QC) are not performed each day of use for moderate/high complexity testing. No QC was performed on 15 of 15 days when the HIV 1/2 Ag/Ab Combo kit was used. 2. Review of Abbott HIV 1/2 Ag/Ab Combo kit QC and patient result logs from 6/2/2022 through 12/11/2023. On the following days patients were tested with no QC performed on the day of patient testing: 6/02/2022 - 1 patient result reported 6/04/2022 - 1 patient result reported 6/07 /2022 - 1 patient result reported 6/16/2022 - 1 patient result reported 7/01/2022 - 1 patient result reported 8/02/2022 - 1 patient result reported 8/10/2022 - 1 patient result reported 8/11/2022 - 5 patient results reported 8/27/2022 - 1 patient result reported 7 /25/2023 - 1 patient result reported 8/12/2023 - 1 patient result reported 9/19/2023 - 1 patient result reported 11/01/2023 - 1 patient result reported 12/07/2023 - 1 patient result reported 12/11/2023 - 1 patient result reported 3. Interview with the lab manager /GS on 2/7/2024 at 12:00 p.m, confirmed that testing personnel was performing two levels of QC (positive and negative) each day of patient testing with the Abbott HIV 1 /2 Ag/Ab Combo kit but did not document the QC as performed. Patient results were manually entered into the LIS (laboratory information system), but QC was not.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of nine of nine ImmunoCard A Toxin C. Diff quality control (QC) and patient records, and interview with the laboratory manager/GS, the laboratory failed to document as performed the QC results for ImmunoCard A Toxin C. Diff in the same manner(reaction) as the patients results. Findings Include: 1. Based on review of the ImmunoCard A Toxin logs, the log sheets included lot numbers for both positive and negative controls, expiration dates, external QC results, patients' results, testing personnel initials, patient labels, time and date. On the log sheet, the testing personnel are instructed to "Select P for Pass or F for Fail for External QC results. Write P for Positive or N for Negative in the patient result field." 2. Review of the ImmnunoCard A Toxin C. Diff log sheets 6/22/2023 through 1/19/2024, revealed the patient's C. Diff results were written on the log as negative or positive. For the QC results, a "P" (pass) or "F" (fail) was circled on the log sheet to indicate the result of the QC. 3. Nine of nine QC and patient results from 6/22/2023 through 1/19/2024, were observed documented on the log sheet as P(pass) or F(fail). 4. Interview with the laboratory manager/GS confirmed this is the documentation protocol used by the testing personnel to report QC and patient C. Diff results.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of Immunohematology quality control (QC) records and the blood bank patient workbook from 6/18/2023 through 12/12/2023, the laboratory failed to document the performance of quality control on each day of patient blood bank testing. Findings include: Review of Immunohematology QC records from 6/18/2023 through 12/12/2023 revealed the laboratory failed to document the performance of quality control, to include the following, to indicate the Immunohematology reagents were functioning properly before patient specimens were analyzed and reported. 1. Positive control for ABO Antisera (ABO grouping) 2. Positive and negative control for Rh Antisera (Rh typing) 3. Positive and negative control for Anti-human globulin sera (Coombs sera) 4. Positive control for antibody screening cells Quality control was not performed on the following days when patients and donors were tested: 6/18 /2023 - Patient #BY96170 - Type, Rh, Crossmatch - 1 unit (W069123132691) 6/30 /2023 - Patient #12/22/97- Type, Rh, Ab Screen 7/15/2023 - Patient #07/31/11- Type, Rh, Ab Screen 7/17/2023 - Unit Retype- W069123133754, W06923119579, W069123107226, W069123133757, W069123130984 7/18/2023 - Patient #9/11/42 - Type, Rh, Ab Screen Crossmatch- 1 unit (W069123119579) 7/31/2023 - Unit Retype- W069123107372, W069123109053, W069123127504, W06912312686, W069123122178, W06912322257, W069123121899, W06912312898, W069123121394, W069123107402, W069123134355 8/14/2023 - Patient #131655- Type, Rh 8/14/2023 - Unit Retype- W069123135591, W069123136081,

	W06912315687, W069123135198, W069123108864, W06912314803, W069123134800, W069123134811 8/23/2023 - Patient #10098 - Type, Rh 8/24/2023 - Unit Retype - W069123136359, W069123131067, W069123121787, W069123787 8 /24/2023 - Type Rh, Ab Screen 8/25/2023 - Patient #08/02/88 - Crossmatch- W06912316359 9/6/2023 - Patient #4/21/77 -Type, Rh, Ab Screen 9/12/2023 - Patient #12/9/94 - Type, Rh, Ab Screen 9/16/2023 - Patient #12/9/94 - Type, Rh 11/13/2023 - Patient #3/7/93 - Type, Rh, Ab Screen 11/19/2023 - Patient #17631 - Type, Rh, Ab Screen 11/23/2023 - Patient #18133 - Type, Rh, Ab Screen 1/20/2022 - No Patient # recorded - Type, Rh, Crossmatch -3 units(W042521092820, W042521092821, W042522004788) 1/25/2022 - Patient #1056753 -Type, Rh, Crossmatch -2 units (W036221563489, W036221564300) 10/27/2022 - Patient #1066892 - Type, Rh, Antibody Screen
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of CMS Casper report and proficiency testing (PT) records, lack of documentation of corrective action, and interview with the laboratory manager /general supervisor (GS) listed on the CMS 209 personnel form, the laboratory director failed to ensure an approved corrective action plan was followed when the laboratory scored below 80% (unsatisfactory) on PT results. Findings Include: 1. Review of CMS Casper report and PT records for 2022 and 2023 revealed the following proficiency test results had scores less than 80%: a. HIV-1p24 Antigen- 2nd event 2022 - 40%; 3rd event 2022- 40%; Revealed 2 of 5 unsatisfactory results. b. Alcohol- 2nd event 2022- 20%; Revealed 1 of 5 unsatisfactory results. c. Acetone- 2nd event 2022 - 60%; Revealed 1 of 5 unsatisfactory results d. Compatibility Blood Bank Tube method - 2nd event 2023 - 60%; Revealed 1 of 5 unsatisfactory results. e. CRP(C-reactive protein) - 2nd event 2023- 0%; Revealed 1 of 5 unsatisfactory results f. Reticulocyte count - 2nd event 2022 - 50% ; 3rd event 2022 - 0% ; Revealed 2 of 5 unsatisfactory results. 2. There was no documentation of corrective action available for review on the day of survey. 3. Laboratory Manager/GS confirmed in an interview on 2/7/2024 at 3:00 p.m. that no corrective action was available for documentation for unsatisfactory results for the analytes listed above.
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 the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory's personnel records, and interview with the lab manager /GS(general supervisor), the laboratory director failed to ensure that, prior to testing patient specimens, five of six testing personnel received the appropriate training for moderate complexity testing and demonstrated performance of all testing operations reliably to provide and report accurate results. Findings include: 1. Review of the CMS 209 personnel form and the laboratory's personnel records revealed the laboratory director failed to ensure that TP #1, #2, #3, #4 and #6 received appropriate training for performing moderate complexity laboratory testing, prior to testing patients' specimens. TP#3 did have a laboratory training form available on the day of survey but was not documented as such by the laboratory director confirming they were competent to perform testing. This was a total of 5 of 6 TP that did not have appropriate training. 2. According to TP personnel records the hire dates of the laboratory personnel are as follows: TP #1- 5/2022 TP #2 - 4/2023 TP #3 - 10/2023 TP #4 - 5/2023 TP #6 - 8/2023 2. In an interview on 2/6/2024 at 11:30 a.m., the GS confirmed initial training for TP #1, #2, #4 and #6 was not available for review the day of the survey and the initial training document available for TP#3 had not been reviewed and ensured of competency by the laboratory director.
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 the number deficiencies for technical consultant responsibilities, the qualified technical consultants listed on the CMS 209 form failed to provide oversight in accordance with 493. 1413 of the subpart. Refer to D6049 - (Failure to review test results, worksheets, QC records, and maintenance.) Refer to D6053 - (Failure to evaluate the performance of individuals responsible for moderate testing at least semiannually.) Refer to D6054 -(Failure to evaluate the performance of individuals responsible for moderate testing annually.)
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 moderate laboratory testing records and interview with TC (technical consultant)#1 and GS (general supervisor), there was no review documented for laboratory records by the Technical Consultant for 21 of 21 months. Finding Include: 1. There was no review documented by the TC from 5/19/2022

	through 2/8/2024 for the following records: a. Beckman Coulter DxH 560 hematology maintenance, quality control (QC) and calibrations b. Beckman Coulter DxH 500 hematology maintenance, QC and calibrations c. Medline Combo serum hCG QC logs d. Laboratory Temperature Logs (refrigerators, freezer and room temperature) logs e. MiniSed ESR QC result log f. Retic Chex II -Streck QC result log g. Access 2 Immunoassay QC, maintenance, calibration and system check report h. ImmunoCard A Toxin C. Diff QC result log i. Abbott HIV 1/2 Ag/Ab Combo QC result log j. Sysmex 600 Coag maintenance checklist, QC, D.dimer calibration k. Beckman Coulter DxC 700-AU chemistry maintenance, QC, calibration, cal verification l. Abbott i STAT QC, calibration verification m. Beckman Coulter AU 480 maintenance, QC, calibration n. Temperature logs(room, refrigerators, freezers) 2. Interview with TC/GS on 2/8/2024 at 11:30 a.m. confirmed there was no available documentation of review of these records by a technical consultant (Quality Control, Preventative Maintenance, Temperature Charts, and Calibrations) by the Technical Consultant for 21 of 21 months.
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 laboratory personnel records, including the (CMS) 209 personnel form and personnel competency evaluations, and an interview with the laboratory manager/GS, the technical consultant (TC) failed to evaluate and document the performance for four of four testing personnel at least semiannually during the first year of moderate complexity testing. Findings include: 1. Review of the laboratory personnel records indicated that semiannual evaluations were due on the following dates: TP #1 6 month due 11/2022 TP #2 6 month due 10/2023 TP #4 6 month due 11 /2023 TP #5 6 month due 9/2022 2. The laboratory manager/GS confirmed in an interview on 2/6/2023 at 12:30 p.m. that the 6 month evaluation/competency was not performed by the TC during the first year of performing moderate complexity testing. 4. The TC failed to document 6 month competency evaluations on 4 of 4 testing personnel.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records including the (CMS) 209 personnel form and personnel competency evaluations, and an interview with the laboratory manager/GS, the technical consultant failed to evaluate the performance for two of six testing personnel at least annually. Findings include: 1. Review of the laboratory personnel records indicated that annual competency evaluations were due on the following dates: TP #1 annual due 11/2023 TP #5 annual due 09/2023 3. The

	laboratory manager/GS confirmed in an interview on 2/6/2024 at 12:30 p.m. that no annual competency evaluations had been documented as performed by the TC for two of six testing personnel at least annually for moderate complexity testing.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 (CMS) 209 personnel form, the laboratory's personnel records, and interview with the lab manager/GS(general supervisor), the laboratory director failed to ensure that, prior to testing patients' specimens, three of four testing personnel had received the appropriate training for high complexity testing and had demonstrated performance of all testing operations reliably to provide and report accurate results. Findings include: 1. Review of the CMS 209 personnel form and the laboratory's personnel records revealed the laboratory director failed to ensure that TP #1, #3, and #6 received appropriate training for performing high laboratory testing, prior to testing patients' specimens. TP#3 did have a laboratory training form available on the day of survey but was not documented as such by the laboratory director confirming they were competent to perform testing. This was a total of 3 of 4 TP that did not have appropriate training. 2. According to TP personnel records the hire dates of the laboratory personnel are as follows: TP #1 - 5/2022 TP #3 - 10/2023 TP #6 - 8 /2023 3. In an interview on 2/6/2024 at 11:30 a.m., the GS confirmed initial training for TP #1 and #6 was not available for review the day of the survey and the initial training document available for TP #3 had not been reviewed and ensured of competency by the laboratory director.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on the number of deficiencies cited for technical supervisor responsibilities, the technical supervisor listed on the CMS 209 form did not provide technical supervision in accordance with 493.1451 of this subpart. Refer to D6123 (Failure to review test results or worksheets, QC records, and preventive records.) Refer to D6127 (Failure to evaluate testing personnel responsible for high complexity testing at least semiannually.) Refer to D6128 (Failure to evaluate testing personnel responsible for high complexity testing annually.)
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(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 on the lood ank refrigerator continuous monitoring recorder graphs, blood bank temperature logs, blood bank quality control log, and transfusion records, the technical supervisor (TS) as listed on the CMS 209 form, failed to document review of records for six of six months. Findings include: 1. Review of the Blood Bank records from 6/8/2023 through 12/23/2023 revealed the following records were not documented as reviewed by the TS. (6 of 6 months not reviewed) a. Blood bank refrigerator continuous monitoring records graphs b. Blood bank refrigerator electronic temperature logs c. Transfusion testing records workbook d. Blood bank QC logs e. Blood bank Product logs
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 laboratory personnel records, including the (CMS) 209 personnel form and personnel competency evaluations, and an interview with the Laboratory Manager/GS (general supervisor), the technical supervisor (TS) failed to evaluate and document the performance for three of four testing personnel semiannually during the first year these individuals performed high complexity testing. Findings include: 1. Review of the CMS 209 laboratory personnel form and personnel records revealed no semiannual evaluations by the technical supervisor for three of four high complexity testing personnel. No documentation of semiannual evaluations of testing personnel: TP #1 6 month due 11/2022 TP #5 6 month due 9/2022 TP #6 6 month due 2/2024 2. During an interview on 2/7/2024 at 11:30 a.m, the laboratory manager/GS confirmed the semiannual evaluations were not performed.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the (CMS) 209 laboratory personnel form and interview with the laboratory manager/GS, the technical supervisor failed to evaluate competency for two of four testing personnel annually for high complexity testing (Immunohematology). Findings include: 1. Based on the laboratory personnel records available for review on 2/6/2024, there were no evaluations available performed by

	the technical supervisor for high complexity testing competency of TP #1 and TP #5 as listed on the CMS 209 form. 2. Interview with the laboratory manager/GS on 2/6 /2024 at 11:30 a.m. confirmed the annual evaluation/competencies for high complexity (Immunohematology) had not been documented as performed by the technical supervisor for TP #1 due 11/2023 and for TP #5 due 3/2023.