Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0710016	09/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bmg Family Physicians Group Foundation, Inc	3091 Kirby Whitten Road, Bartlett, TN	

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	During a recertification survey on 09/27/23, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1215 Condition: Hematology 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 the laboratory's proficiency testing (PT) records and staff interview, the testing personnel who performed the microscopy portion of the PT events for 2022 did not sign the attestation statements (three of three events from 2022). The findings include: 1. Review of the laboratory's proficiency testing records revealed the attestation statements for 2022 events one, two and three were not signed by the persons who performed the microscopy portion of the PT events. 2. Interview with the laboratory liaison on 09/27/23 at 9:40 am confirmed that the testing personnel who performed the microscopy portion of the PT events for 2022 did not sign the attestation statements.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency

	testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's PT records and staff interview, the laboratory failed to ensure PT records contained the identity of the person who performed the microscopy portion of the PT events for 2022 events one, two, and three (three of three events from 2022). The findings include: 1. Review of the PT records for 2022 events one, two and three revealed the records did not contain the identity of the person who performed the microscopy portion of the PT events. 2. Interview with the laboratory liaison on 09/27/23 at 9:40 am confirmed the laboratory failed to ensure the PT records contained the identity of the person who performed the microscopy portion of the PT events from 2022 events one, two and three.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manual, the Centers for Medicare and Medicaid Services Laboratory Personnel Report (Form CMS 209), testing personnel records, observation of the laboratory, review of environmental records, manufacturer instructions for use, review of quality control records, the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), lack of documents, quality assurance records, and staff interviews, the laboratory failed to ensure ensure it followed its' own testing personnel policy (Refer to D5209), failed to ensure the laboratory procedure for CBC included procedures to follow when changing control lots and failed to include proceures to follow for patient results flagged by the CBC instrument (Refer to D5401), failed to ensure collection tubes were not used past their expiration date (Refer to D5417), failed to ensure quality control (QC) was monitored over time (Refer to D5441), failed to ensure QC ranges were verified (D5469), and failed to ensure its' quality assessment (QA) processes were adequate to detect, correct, and prevent problems with quality control (Refer to D5793).
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 procedure manual, review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel records and staff interview, the laboratory failed to follow their own procedure for training and six month competency assessment for testing person number six in 2020 (one of nine new testing personnel). The findings include: 1. Review of the laboratory's testing personnel competency assessment policy revealed that new testing personnel would be checked off on all aspects of lab duties during their training period. The policy also required a competency assessment at six months after hire. 2. Review of the Form CMS-209 from the previous survey conducted on 01 /16/20 with comparison to the Form CMS-209 for the current survey revealed testing person number six was new since the last survey. 3. Review of the laboratory's testing personnel records revealed testing personnel number six had a hire date of 04/27/20. There was no documentation of initial training or six month competency. 4. Interview with the lab liaison on 09/27/23 at 12 pm revealed the following: Testing person number six was previously employed at the facility and was previously trained. She came back in April 2020. She did not go back through initial training or have a six month competency assessment. This confirmed the survey findings.
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 observation of the laboratory, review of the laboratory procedure manual and interview with the laboratory liaison, the laboratory procedure for Complete Blood Count failed to include procedures for setting quality control (QC) limits in the Sysmex XS 1000i instrument and procedures to follow for results with instrument flags. The findings include: 1. Observation of the laboratory on 09/27/23 at 9:50 am revealed two Sysmex XS 1000i instruments in use for patient testing, one in the main laboratory (serial #74898) and one in the nursing laboratory (serial #74897). A percent limit guide was posted on the front of the instruments. 2. Review of the procedure titled "CBC performed on Sysmex XS-1000i" revealed the procedure did not include instructions for entering and setting CBC control limits in the Sysmex XS 1000i instruments or steps to follow for results that are flagged by the instrument. 3. Interview with the laboratory liaison on 09/27/23 at 5 pm revealed the following: The laboratory uses the manufacturer evidence based percent limits to set their quality control ranges. The percent limits are posted on the instrument. The approved procedure did not include procedures/instructions for entering and setting the control limits in the Sysmex XS 1000i CBC instrument. She stated the lab repeats results that are flagged, but procedures to follow were not included in the approved procedure. This confirmed the survey findings.
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 of the laboratory, review of the laboratory's environmental monitoring records, the manufacturer instructions for use, and interview with the laboratory liaison, the laboratory failed to define ranges for humidity and room temperature that was consistent with manufacturer requirements for operation of the Sysmex XS 1000i Complete Blood Count (CBC) instrument from 06/01/23 to the date of the survey on 09/27/23. The findings include: 1. Observation of the laboratory on 09 /27/23 at 9:50 am revealed two Sysmex XS 1000i instruments in use for patient testing for CBC, one in the main laboratory (serial # 74898) and one in the nursing laboratory area (serial #74897). 2. Review of the laboratory's environmental monitoring records revealed a humidity range of 20-85% and a room temperature range of 15-35 degrees Celsius. 3. Review of the Sysmex XS 1000i manufacturer instructions for use revealed an operating humidity range of 30-85% and an ambient temperature range of 15-30 degrees Celsius. 4. Interview with the laboratory liaison on 09/27/23 at 5 pm confirmed the laboratory did not define humidity and room temperature ranges that were consistent with the Sysmex XS 1000i manufacturer requirements.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the nursing laboratory area and staff interview, the laboratory failed to label the saline used for collecting and transporting patient samples for wet prep on the date of the survey (09/27/23). The findings include: 1. Observation of the nursing laboratory area on 09/27/23 at 10:15 am revealed clear vials of liquid in a rack inside a drawer that were used for collection and transport of patient samples for wet prep. The vials were not labeled. 2. During an interview with the laboratory liaison on 09/27/23 at 10:15 am, the lab liaison communicated the following: The vials in the drawer were saline that were used for collecting and transporting wet prep samples to the lab. The liquid in the vials had been poured off from a master container, but were not labeled. This confirmed the survey findings.
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 of the laboratory and staff interview, the laboratory failed to ensure tubes used for capillary collection of Complete Blood Count (CBC) were not used past their expiration date on the date of the survey (09/27/23). The findings include: 1. Observation of the laboratory on 09/27/23 at 9:50 am revealed tubes used for capillary collection of CBCs in the phlebotomy chair drawer that were expired (lot#1363407, expiration date of 06/30/23). The tubes were discarded on the date of the survey. 2. Interview with the lab liaison on 09/27/23 at 9:55 am confirmed the expired tubes in the drawer were there to be used if the laboratory collected a CBC by fingerstick.
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 observation of the laboratory, review of QC records, the CMS-116, and staff interview, the laboratory failed to print cumulative quality control for the two Sysmex XS 1000i instruments in use for patient CBC testing in 2021, 2022, and 2023, resulting in the laboratory not ensuring the QC ranges used were appropriate to detect errors and no retention of the QC ranges that were in use at the time of QC performance in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 09/27/23 at 9:50 am revealed two Sysmex XS 1000i CBC instruments in use for patient testing, one in the main laboratory (serial #74898) and one in the nursing lab (serial # 74897). 2. Review of the laboratory's QC records revealed no records of cumulative quality control records to monitor accuracy and precision over time from the past two years. 3. Cumulative reports printed after correction of QC limits for lots in the lab and nursing instrument revealed dates with QC that was outside the laboratory's acceptable range. (Refer to D5469) 4. Review of the CMS-116 annual test volume estimates revealed approximately 4,963 patients are reported annually, resulting in approximately 9,926 patient reported during the period when the cumulative reports were not printed. 5. Interview with the office manager on 09/27/23 at 3:00 pm confirmed there were no cumulative printouts of the laboratory's CBC quality control for either instrument from 2021, 2022, or 2023.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When

control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of quality control (QC) records, the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), and staff interview, the laboratory failed to verify the use of correct quality control ranges for a period from 02/28/23 to the date of the survey (09/27/23) for the laboratory instrument, and a period from 04/17/23 to the date of the survey (09/27/23), resulting in the potential for reporting of patient CBC results with unacceptable quality control. Approximately 2,480 patient CBCs were performed during the period when the incorrect QC limits were in use. The findings include: 1. Observation of the laboratory on 09/27/23 at 9:50 am revealed two Sysmex XS1000i instruments in use for patient CBC testing (serial #74898 in the main lab, serial #74897 in the nursing lab). Taped to both instruments was a document titled "XS Control limits." The limit range % posted on the instruments for use by the lab for setting QC ranges were as follows for selected parameters: Level 1 Level 2 Level 3 RBC 5.0 4.0 4.0 HGB 6.0 4.3 4.2 HCT 6.0 5.1 5.0 PLT 23 12 9.7 WBC 11.4 7.8 7.8 NE% 11.1 8.9 8.1 LY% 12.1 9.1 7.7 MO% 35 24 19.7 EO% 29.3 28.3 28.4 BA% 34.9 31.1 31.1 All other CBC parameters had specific/defined limit range percents as well. 2. Review of the laboratory's available quality control records/lots that were still maintained in the lab's instruments revealed the following: Serial #74898 (main lab instrument) Lot number 30380804, 30380805, 30380806, date from = 02/28/23 date to: 04/28/23. The limit range % was set at 100% for all analytes, resulting in the following QC ranges: Level one (30380804): RBC=0.0 - 5.22, HGB=0.0 - 12.2, HCT=0.0 - 39, PLT=0 - 106, WBC=0.0 - 5.98, NE%=0.0 - 72.2, LY%=0.0 - 79, MO%=0.0 - 19.8, EO%=0.0 - 19.8, BA%=0.0 -10.8. Level two (30380805): RBC=0.0 - 8.98, HGB=0.0 - 25.6, HCT=0.0 - 78.4, PLT=0 - 464, WBC=0.0 - 13.84, NE%=0.0 - 83.2, LY%=0.0 - 65.0, MO%=0.0 - 19.2, EO%=0.0 - 20.2, BA%=0.0 - 12.4. Level three (30380806): RBC=0.0 - 10.79, HGB=0.0 - 32.8, HCT=0.0 - 98.4, PLT=0 - 1114, WBC=0.0 - 13.84, NE%=0.0 - 83.2, LY%=0.0 - 65.0, MO%=0.0 - 19.2, EO%=0.0 - 20.2, BA%=0.0 - 12.4. Lot numbers 30940804, 30940805, 30940806, date from: 04/17/23, date to: 06/23/23. The limit range % was set at 100% for all analytes, resulting in the following QC ranges: Level one (30940804): RBC=0.0 - 5.12, HGB=0.0 - 12.4, HCT=0.0 - 39.8, PLT=0 - 106, WBC=0.0 - 5.92, NE%=0.0 - 75.8, LY%=0.0 - 76.4, MO%=0.0 - 17.8, EO%=0.0 - 18.4, BA%=0.0 - 11.6. Level two (30940805): RBC=0.0 - 8.76, HGB=0.0 - 24.0, HCT=0.0 - 73.6, PLT=0 - 454, WBC=0.0 - 13.74, NE%=0.0 - 83.0, LY%=0.0 - 66.6, MO%=0.0 - 18.0, EO%=0.0 - 19.8, BA%=0.0 - 12.6. Level three (30940806): RBC=0.0 - 10.86, HGB=0.0 - 31.6, HCT=0.0 - 95.8, PLT=0 - 1096, WBC=0.0 - 32.04, NE%=0.0 - 89.8, LY%=0.0 - 56.2, MO%=0.0 - 18.2, EO%=0.0 - 21.6, BA%=0.0 - 14. Lot numbers 31940804, 31940805, 31940806, date from: 06/12/23, date to: 08/18/23. The limit range % was set at 100% for all analytes, resulting in the following QC ranges: Level one (31940804): RBC=0.0 - 5.06, HGB=0.0 - 11.6, HCT=0.0 - 37.0, PLT=0 - 104, WBC=0.0 - 5.98, NE%=0.0 - 76.6, LY%=0.0 - 74.6, MO%=0.0 - 19.6, EO%=0.0

	- 18.2, BA%=0.0 - 11.2. Level two (31940805): RBC=0.0 - 8.62, HGB=0.0 - 24.2, HCT=0.0 - 73.2, PLT=0 - 426, WBC=0.0 - 14.04, NE%=0.0 - 82.2, LY%=0.0 - 65.2, MO%=0.0 - 20.2, EO%=0.0 - 19.8, BA%=0.0 - 12.6. Level three (31940806): RBC=0. 0 - 10.6, HGB=0.0 - 32.2, HCT=0.0 - 96.0, PLT=0 - 1054, WBC=0.0 - 34.02, NE%=0. 0 - 88.0, LY%=0.0 - 56.2, MO%=0.0 - 20.6, EO%=0.0 - 21.4, BA%=0.0 - 13.8. Lot numbers 32050804, 32050805, 32050806, date from: 08/07/23, date to: 09/27/23 (survey date). The limit range % was set at 100% for all analytes, resulting in the following QC ranges: Level one (31940804): RBC=0.0 - 5.14, HGB=0.0 - 12.8, HCT=0.0 - 39.6, PLT=0 - 110, WBC=0.0 - 6.08, NE%=0.0 - 79.8, LY%=0.0 - 79.8, MO%=0.0 - 18.6, EO%=0.0 - 17.8, BA%=0.0 - 10.8 Level two (31940805): RBC=0.0 - 8.62, HGB=0.0 - 24.4, HCT=0.0 - 73.4, PLT=0 - 462, WBC=0.0 - 13.56, NE%=0.0 - 81.6, LY%=0.0 - 67.0, MO%=0.0 - 29.6, EO%=0.0 - 19.6, BA%=0.0 - 12.2. Level three (31940806): RBC=0.0 - 10.54, HGB=0.0 - 32.6, HCT=0.0 - 96.4, PLT=0 - 1100, WBC=0.0 - 31.64, NE%=0.0 - 88.4, LY%=0.0 - 57.2, MO%=0.0 - 19.0, EO%=0.0 - 21.6, BA%=0.0 - 13.8. Serial #74897 (nursing lab instrument) The same issue with incorrect QC limits (% limits set at 100%) was observed for the nursing unit instrument for the lots that were still maintained in the instrument. Lot numbers 30940804, 30940805, 30940806, date from: 04/17/23, date to: 06/23/23. The limit range % was set at 100% for all analytes, resulting in QC ranges that approximated the ones observed for the laboratory instrument. Lot numbers 31940804, 31940805, 31940806, date from: 06/12/23, date to: 08/18/23. The limit range % was set at 100% for all analytes, resulting in QC ranges that approximated the ones observed for the laboratory instrument. Lot numbers 32050804, 32050805, 32050806, date from: 08/07 /23, date to: 09/27/23 (survey date). The limit range % was set at 100% for all analytes, resulting in QC ranges that approximated the ones observed for the laboratory instrument (see above). The QC limit range % for both instruments was corrected before the survey was concluded for all existing lots in the instruments. 3. Review of the Form CMS 116 revealed an estimated annual patient CBC test volume of 4963, resulting in approximately 2,480 patients reported during the period when incorrect QC ranges were in use. 4. Interview with the laboratory liaison on 09/27/23 at 5 pm confirmed the laboratory failed to ensure the control ranges in use on the laboratory instrument from 02/28/23 to the date of the survey on 09/27/23 were verified before placing into use, and failed to ensure the control ranges in use on the nursing instrument from 07/17/23 to the date of the survey on 09/27/23 were verified before placing into use. Word Key: Quality Control (QC) %=percent RBC=Red Blood Cell HGB=Hemoglobin HCT=Hematocrit PLT=Platelet WBC=White Blood Cell NE%=Neutrophil % LY%=Lymphocyte % MO%=Monocyte % EO% =Eosinophil % BA%=Basophil %
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 QC records, lack of documents, quality assessment checklist, and interview with the office manager, the laboratory's QA process was ineffective in identifying, correcting and preventing problems with the

	laboratory's QC ranges for CBC in 2023 (Refer to D5469) and was ineffective in correcting problems with printing and retaining cumulative quality control data (Refer to D5441). The findings include: 1. Review of the laboratory's QC records revealed the laboratory was using incorrect QC ranges for both the nursing lab instrument and the main laboratory instrument for twenty-one of twenty-one lots reviewed from 2023. (Refer to D5469) 2. There were no cumulative QC prints for either the laboratory or nursing instrument on the date of survey for 2021, 2022, or 2023. (Refer to D5441) 3. Review of the laboratory's quarterly quality assessment checklist revealed that printing and review of the QC ranges and the laboratory's cumulative quality control was not included on the review worksheet. 4. Interview with the office manager on 09 /27/23 at 5 pm revealed the following: The QA review worksheet is completed by the office manager and signed by the lab director. One date is picked and the QC is checked to see if it is in range on that date. She could not locate any cumulative CBC QC records for 2021, 2022, or 2023. This confirmed the laboratory's QA review process was ineffective in identifying, correcting and preventing problems with the laboratory's QC ranges and retention of the cumulative QC reports.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of the Allegation of Compliance from the 06/05/18 recertification survey, the Centers for Medicare and Medicaid Services Casper Report 0155D (CMS 155), the laboratory's PT records, the laboratory's QC records, the laboratory's testing personnel policy and testing personnel records, the laboratory director failed to ensure the Allegation of Compliance from the 06/05/18 survey of the lab was maintained (Refer to D6004), failed to ensure laboratory was enrolled in PT for regulated CBC analytes for 2023 event one (Refer to D6015), failed to ensure the laboratory's QC program was maintained (Refer to D5441, D5469, and D6020), failed to ensure testing personnel received training for performance of CBC (Refer to D5209 and D6029), and failed to ensure the laboratory's competency assessment policy was followed (Refer to D5209 and D6030).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by:

	Based on review of the statement of deficiencies from a survey conducted on 06/05 /18, the laboratory's allegation of compliance, the laboratory's QC records and interview with the lab liaison, the laboratory director failed to ensure the Allegation of Compliance as submitted for the 06/05/18 survey was maintained (Refer to D5469 and D6020). The findings include: 1. Review of the Statement of Deficiencies cited for the 06/05/18 recertification survey of the laboratory revealed the laboratory director was cited for same deficiency under D6020 for not ensuring QC ranges were maintained. 2. Review of the Allegation of Compliance submitted for deficiencies cited revealed the following submitted as the plan of correction: Written procedures were developed to ensure ranges were verified every time a new QC file is made. A checkoff sheet was created to ensure all necessary documentation was accounted for before forwarding to the lab director for review. Monitoring would occur as QC results were printed (at least quarterly). 3. Review of the laboratory's QC records revealed the use of incorrect QC ranges in both the nursing lab instrument and the main lab instrument on the date of the survey. 4. Interview with the lab liaison on 09 /27/23 at 5 pm confirmed the Allegation of Compliance as submitted for 06/05/18 survey was not maintained.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Services Casper Report 0155D (CMS 155), the laboratory's proficiency testing records, and staff interview, the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for the first event of 2023. The findings include: 1. Observation of the laboratory on 09/27/23 at 9:50 am revealed two Sysmex XS 1000i CBC instruments in use for patient testing. 2. Review of the CMS 155 revealed no scores for hematology for 2023 event one. 3. Review of the laboratory's proficiency testing records revealed no PT records for 2023 event one for hematology. The 2023 PT program enrollment form did not include enrollment for 2023 event one for hematology. 4. Interview with the laboratory liaison on 09/27/23 at 5:00 pm confirmed the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for hematology for the first event of 2023 with patient testing for CBC being performed.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of records, review of the QC ranges in the two laboratory CBC instruments, calibration records for both instruments, and interview with the laboratory liaison, the laboratory director failed to ensure the laboratory's QC program was maintained in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 09/27/23 at 9:50 am revealed two Sysmex XS 1000i CBC instruments in use for patient testing for CBC. Posted on the both instruments was the limit range percent used by the laboratory for setting quality control ranges. 2. There were no cumulative QC records available on the date of the survey from 2021, 2022, or 2022. (Refer to D5441) 3. Review of the QC ranges in both the lab instrument and the nursing instrument revealed incorrect QC ranges in both instruments for the current lot as well as previous lot numbers (refer to D5469). 4. Review of the calibration records for both instruments revealed no review by the lab director for 13 of 13 calibrations from 2021, 2022, and 2023. 5. Interview with the laboratory liaison on 09/27/23 at 5 pm confirmed the laboratory director failed to ensure the laboratory's QC program was maintained in 2021, 2022, and 2023.
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 testing personnel records, and staff interview, the laboratory director failed to ensure testing person number six received training for performing CBC testing in 2020. (Refer to D5209) The findings include: 1. Review of the testing personnel records revealed the following: Testing person number six hire date was 04 /27/20. There was no documentation of initial training and demonstrated accuracy prior to performing patient testing for CBC. 2. During an interview with the laboratory liaison on 09/27/23 at 12 pm the following was communicated: Testing person number six performs patient testing for CBC. Testing person number six was previously employed and came back to the facility in 2020. Testing person six was not retrained when they were rehired. This confirmed the survey findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical

	phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, testing personnel records, patient test reports, and staff interview, the laboratory director failed to perform and ensure the laboratory's competency assessment policy was followed in 2021, 2022, and 2023 when testing person number one performed microscopy testing for urine microscopics, wet prep and potassium hydroxide (KOH) in 2021, 2022, and 2022 without competency assessments; testing person number three competency for urine microscopics, wet prep and KOH was not performed by the lab director, and six-month competency assessment was not performed for testing person number six for performance of CBC testing. (Refer to D5209) The findings include: 1. Review of the laboratory's testing personnel competency assessment policy revealed that new testing personnel would have a competency assessment six months after hire and then annually thereafter. 2. Review of the testing personnel records revealed the following: Testing person number one: Performs patient testing for urine microscopics, KOH and wet prep. No competency assessments were performed in 2021, 2022 or 2023 for performance of those tests. Testing person number three: The six month competency assessment performed on 01/06/23 for testing person number three for performance of urine microscopics, KOH, and wet prep was not performed by the laboratory director. The competency was performed by testing person number two who was not the laboratory director and did meet the regulatory requirements for a technical consultant. Testing person number six: Hire date of 04/27/20. No documentation of a six-month competency assessment for performance of CBCs. 3. Review of patient test reports revealed the following: Testing person number one: Patient #11771335 wet prep reported by testing person number one on 01/27/22; patient #12603284 urine microscopic reported by testing person number one on 04/28/22; patient #12948046 KOH reported by testing person number one on 10/03/22; patient #13850794 urine microscopic reported by testing person number one on 08/23/23. Testing person number three: Patient #12671208 wet prep reported by testing person number three on 05/26/23. 4. Interview with the laboratory liaison on 09/27/23 at 12 pm confirmed the following: Testing person number one performs urine microscopics, KOH and wet preps. There were no competency assessments for performance of those tests in 2021, 2022, and 2023. Testing person number three is checked off and performs microscopy testing to include urine microscopics, KOH and wet preps. The 6 month competency assessment for microscopy was not performed by the lab director. Testing person number six left employment and then came back. Testing person number six was not assessed for competency at the six-month interval when they were rehired. This confirmed the survey findings.