Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0669427	02/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Muhammed I Khokar Md	608 New Hope Road Suite 3, Princeton, WV	

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	An announced CLIA recertification survey was conducted at Muhammad I Khokar MD on February 27, 2020 by the West Virginia Office of Laboratory Services. The facility was surveyed to assess compliance with regulations under the Federal Clinical Laboratory Improvement Amendments (CLIA) 42 CFR 493. Specific deficiencies cited are explained below.
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 a review of the laboratory Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and an interview with the laboratory director, the testing personnel (TP) and/or laboratory director (LD) failed to sign the attestation statements for 2 of 3 MLE PT testing events in 2019. Findings: 1. A review of MLE PT records for 2019 identified 2 of 3 testing events that lacked the attestation signatures of the TP and/or LD. a. The 2019 MLE-M2 testing event had an attestation statement that lacked the signature of the TP and the LD. b. The 2019 MLE-M3 testing event had an attestation statement that was signed by the LD, but lacked the signature of the TP. 2. During an interview with the LD, on 2/27/2020 at approximately 12:00, the LD stated that attestation forms had not been handled properly for the 2 testing events of 2019, but would ensure all parties signed in the future.
D2128	HEMATOLOGY CFR(s): 493.851(e)

	(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and an interview with the laboratory director (LD), the laboratory failed to perform and document remedial action for unacceptable analyte scores in 2 of 3 testing events of 2019. Findings: 1. A review of 2019 MLE PT records identified 2 unsuccessful analyte scores for the MLE-M2 testing event. a. Specimen HD-7 had a result of 0.6 for monocytes and the acceptable range was 7.0-16.4. b. Specimen HD-7 had a result of 1.5 for granulocytes and the acceptable range was 25.6-34.9. 2. A review of 2019 MLE PT records identified 2 unsuccessful analyte scores for the MLE-M3 testing event. a. Specimen HD-13 had a result of 0.4 for monocytes and the acceptable range was 2.5-7.8. b. Specimen HD-13 had a result of 4.8 for granulocytes and the acceptable range was 60.3-68.7. 3. It was observed thru record review of the 2019 MLE-M2 and MLE-M3 PT events by the state surveyor that no documentation of remedial action regarding the unacceptable analyte scores could be located. 4. During an interview with the LD, on 2/27/2020 at approximately 12:00, the LD stated there was no documented investigation of the unacceptable analyte scores for the MLE-M2 and MLE-M3 PT events.
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 a review of testing personnel 1 (TP1) competency records, TP1 employee files, laboratory job descriptions, and an interview with the technical consultant (TC), the laboratory failed to establish and follow written policies and procedures (P&P) assessing testing personnel competency and problem solving for each testing platform. Findings: 1. A review of TP1 competency records identified 1 documented competency for TP1 dated 02/12/2020. The laboratory TP competency form did not include evidence of problem solving. 2. A review of TP1 employee files identified the hire date of TP1 documented as 4/24/2019. 3. A review of "Laboratory Policy & Procedure Subject: Job Descriptions" stated that employee competency was to be assessed semi-annually the first year of testing and annually thereafter by the Technical Consultant (TC). 4. During an interview with the TC, on 2/27/2020 at approximately 12:00 PM, the TC stated that the 2/12/2020 competency on TP1 was the only documented competency performed on TP1.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of laboratory written policies and procedures (P & P), calibration records for the ACTDiff2 analyzer, and an interview with testing personnel 1 (TP1) and the laboratory director (LD), the laboratory failed to perform and document calibration on the hematology ACTDiff2 analyzer in accordance with established laboratory processes. Findings: 1. A review of written P&Ps in the M.I Khokar MD Laboratory Policy and Procedure manual identified the QA Program P&P as stating "The Beckman Coulter ActDiff2 is to be calibrated every 6 months and calibrator is set on auto delivery. Calibration will be performed as needed if technical failure noted and if indicated." 2. A review of calibration records for the ActDiff2 from January 2018 thru February 2020 identiifed calibration as performed and documented on the following dates: 01/05/2018, 08/31/2018, 02/01/2019, and 02/24/2020. There is no documentation of calibration being performed at the required 6 month interval after the 02/01/2019 calibration. 3. During an interview with TP1, on 02/27/2020 at approximately 10:00 AM, the state inspector asked if the calibration records reviewed were the only calibrations performed on the ACTDiff2 analyzer and TP1 stated that the calibration done 02/24/2020 was the only one she performed and documented. TP was hired 04/24/2019. 4. During an interview with the LD, on 02/27/2020 at approximately 12:00 PM, the LD stated that the calibrators for the ACTDiff2 analyzer were on autodelivery and he was not aware the calibrations had not been performed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for

	verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of laboratory calibration records, patient testing logs, and quality control (QC) records for the ACTDiff2 hematology analyzer and an interview with testing personnel 1 (TP1), the laboratory failed to satisfy the calibration verification requirement, and did not meet the criteria for hematology analyzer exception. Findings: 1. A review of calibration records for the ACTDiff2 from January 2018 thru February 2020 identified a failure to perform and document calibration every 6 months as required by the manufacturer instructions and the written policy and procedures. Refer to D5437. 2. A review of QC records and laboratory patient testing logs from December 2019 and February 2020, identified 17 of 28 days of patient testing that had no documentation of at least 2 levels of QC being performed daily to meet the automated hematology analyzer exception for calibration verification. Refer to D5441. a. During 10 of 13 days of patient testing in February 2020 only 1 level of hematology QC was documented and performed. b. During 7 of 15 days of patient testing in December 2019 no hematology QC was documented and performed. 3. During an interview with TP1, on 2/27/2020 at approximately 10:20 AM, the TP1 stated that QC records and calibration records reviewed by the state surveyor were the only documentation of QC and calibrations performed on the ACTDiff2 hematology analyzer. 4. During an interview with the LD, on 2/27/2020 at approximatley 12:30, the LD stated the calibration materials were on auto delivery and that QC is reviewed.
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 upon a review of written laboratory policies and procedures (P&P), quality control (QC) records for the ACTDiff2 hematology analyzer, patient testing logs, and an interview with the testing personnel (TP1) and laboratory director (LD), the laboratory failed to perform and document QC at the specified and required frequency. Findings: 1. A review of the quality assessment (QA) policy in the laboratory P&P manual stated 3 levels of QC were to be ran and evaluated for acceptability before patient testing was to begin. 2. A review of QC records and laboratory patient testing logs from December 2019 and February 2020, identified 17 of 28 days of patient testing that had no documentation of at least 2 levels of QC being performed. a. During 10 of 13 days of patient testing in February 2020 only 1 level of hematology QC was documented and performed. b. During 7 of 15 days of patient testing in December 2019 no hematology QC was documented and performed.

	3. During an interview with TP1, on 2/27/2020 at approximately 11:00 AM, the TP1 stated there were days she only ran one level of QC due to "patients waiting to be seen by the doctor in the morning" and not having a working printer. 4. During an interview with the LD, on 02/27/2020 at approximately 12:30 PM, the LD stated he reviewed QC and will make sure all 3 levels are ran and verified for acceptability each day before patient 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 upon a review of written laboratory policies and procedures (P&P), quality control (QC) records for the ACTDiff2 hematology analyzer, patient testing logs, and an interview with the testing personnel (TP1) and laboratory director (LD), the laboratory failed to perform and document QC at the specified and required frequency. Findings: 1. A review of the quality assessment (QA) policy in the laboratory written P&P stated 3 levels of QC were to be ran and evaluated for acceptability before patient testing was to begin. 2. A review of QC records and laboratory patient testing logs from December 2019 and February 2020, identified 17 of 28 days of patient testing that had no documentation of at least 2 levels of QC being performed. a. During 10 of 13 days of patient testing in February 2020 only 1 level of hematology QC was documented and performed. b. During 7 of 15 days of patient testing in December 2019 no hematology QC was documented and performed. 3. During an interview with TP1, on 2/27/2020 at approximately 11:00 AM, the TP1 stated there were days she only ran one level of QC due to "patients waiting to be seen by the doctor in the morning" and not having a working printer. 4. During an interview with the LD, on 02/27/2020 at approximately 12:30 PM, the LD stated he reviewed QC and will make sure all 3 levels are ran and verified for acceptability each day before patient testing.
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 a review of laboratory written policy and procedures (P&P), quality control (QC) records, calibration records, proficiency testing (PT) records, and testing personnel (TP) competency records, the laboratory director (LD) failed to provide overall management and direction of the laboratory. Findings: 1. A review of laboratory QC records for the ACTDiff2 hematology analyzer identified 17 of 28 days of patient testing that had no documentation of at least 2 levels of QC being performed and evaluated for acceptability before patient testing began. Refer to

	D5441 and D5447. 2. A review of 2018, 2019, and 2020 calibration records for the ACTDiff2 hematology analyzer identified a failure to perform and document calibration every 6 months as required by the manufacturer and the written policies and procedures. Refer to D5437 and D5439. 3. A review of 2019 Medical Laboratory Evaluation (MLE) PT records identified a failure to investigate and document any remedial action for unacceptable analyte scores for 2 of 3 Hematology testing events. Refer to D2128. 4. A review of 2019 MLE PT records identified a failure of both the LD and testing personnel to sign attestation statements for 2 of 3 testing events. Refer to D2009. 5. A review of TP competency records identified a failure to perform and document TP competency in adherence to established P&P of the laboratory. Refer to D5209.
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 a review of personnel files of testing personnel (TP), patient testing logs, quality control (QC) records, and calibration records,the laboratory director (LD) failed to provide effective administration of the laboratory, which includes documented assessment of employee competency and intitial training, ensuring accurate test performance with adherence to QC requirements, and compliance with the regulations. Findings: 1. Refer to D6000.
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 a review of laboratory Medical Laboratory Evaluation (MLE) proficiency testing (PT) records, the laboratory director failed to ensure that all PT reports are reviewed to identify any unacceptable responses and any issues that require corrective action. Findings: 1. Refer to D2128.
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 a review of laboratory written policies and procedures (P&P), quality control (QC) records, calibration records, and an interview with testing personnel (TP1) and the laboratory director (LD), the LD failed to ensure that the quality control (QC) program of the laboratory for the ACTDiff2 hematology analyzer was maintained. Findings: 1. Refer to D5441, D5447, D5437, and D5439.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on a review of the laboratory testing personnel (TP) competency documentation form and an interview with the technical consultant (TC), the laboratory failed to include the assessment of problem solving skills in the testing personnel competency process. Findings: 1. The employee competency form used to document TP competency was reviewed by the surveyor. The form lacked the assessment of problem solving skills. 2. During an interview with the TC, on 2/27 /2020 at approximately 12:00 PM, the TC stated that the assessment of problem solving skills for TP will be included on the employee competency documentation and evaluation of TP performance.
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 a review of testing personnel 1 (TP1) competency records, TP1 employee files, laboratory job descriptions, and an interview with the technical consultant (TC), the TC failed to establish and follow written policies and procedures (P&P) assessing testing personnel competency and problem solving for each testing platform. Findings: 1. A review of TP1 competency records identified 1 documented competency for TP1 dated 02/12/2020. The laboratory TP competency form did not include evidence of problem solving. 2. A review of TP1 employee files identified the hire date of TP1 documented as 4/24/2019. 3. A review of "Laboratory Policy & Procedure Subject: Job Descriptions" stated that employee competency was to be

	assessed semi-annually the first year of testing and annually thereafter by the Technical Consultant (TC). 4. During an interview with the TC, on 2/27/2020 at approximately 12:00 PM, the TC stated that the 2/12/2020 competency on TP1 was the only documented competency performed on TP1.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on a review of written laboratory policies and procedures (P&P), quality control (QC) records, and an interview with testing personnel (TP1), the moderate complexity testing personnel did not adhere to the established laboratory QC and calibration processes and failed to perform and document the required actions. Findings: 1. A review of the "M I Khokar Laboratory Policy and Procedure Manual" revealed a P&P tiled "QA Program" that stated 3 levels of QC were to be ran and evaluated for acceptability before patient testing was to begin. 2. A review of QC records and laboratory patient testing logs from December 2019 and February 2020, identified 17 of 28 days of patient testing that had no documentation of at least 2 levels of QC being performed. a. During 10 of 13 days of patient testing in February 2020 only 1 level of hematology QC was documented and performed. b. During 7 of 15 days of patient testing in December 2019 no hematology QC was documented and performed. 3. During an interview with TP, on 2/27/2020 at approximately 11:00 AM, the TP stated there were days she only ran one level of QC due to "patients waiting to be seen by the doctor in the morning" and not having a working printer. 4. During an interview with the LD, on 02/27/2020 at approximately 12:30 PM, the LD stated he reviewed QC and will make sure all 3 levels are ran and verified for acceptability each day before patient testing.