Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0704194	03/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mid-Valley Internists Pa	1330 E 6th St Suite 101, Weslaco, TX	

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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems D6000 - 42 C.F.R. 493.1405 Condition: Laboratory Director; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of the the laboratory director signing 2 of 6 attestation statements and testing personnel signing 3 of 6 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's (API) proficiency testing records from 2016 (events 1, 2, and 3) and 2017 (events 2 and 3) and proficiency testing records from the Wisconsin State Laboratory of Hygiene (WSLH) (2017 event 1) revealed the laboratory failed to have documentation of the following signatures on attestation

	statements: a) Laboratory Director 2016 API Event 2 2017 WSLH Event 1 b) Testing Personnel 2016 API Event 2 2017 WSLH Event 1 2017 API Event 2 2. The laboratory was asked to provide documentation of the laboratory director and testing personnel signing the identified attestation statements. No documentation was provided. 3. An interview with the medical assistant on 03/13/2018 at 1330 hours in the break room - after her review of the records- confirmed the findings.
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 submitted Form CMS 209, review of the laboratory's proficiency testing records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of all testing personnel who routinely performed patient testing of participating in proficiency testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 03/13/2018) revealed the laboratory identified 3 test personnel. They were: a) Testing personnel number 1 employed 11/04/2014 to current b) Testing personnel number 2 employed 04/20/2017 to current c) Testing personnel number 3 employed 10/04/2017 to 01/19/2018 2. A review of the laboratory's proficiency testing records from 2016 and 2017 revealed testing personnel number 1 was documented as having performed testing of the proficiency samples for 6 of 6 events reviewed. 3. The laboratory was asked to provide documentation of testing personnel number 2 and testing personnel number 3 participating in proficiency testing. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 03/13/2018 at 1330 hours in the break room revealed she was the only testing personnel who performed testing on proficiency samples. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 03/21/2016
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of the review of the results for 2 of 6 events. The findings were: 1. A review of the laboratory's American Proficiency Institute's (API) proficiency testing records from 2016 (events 1, 2, and 3) and 2017 (events 2 and 3) and proficiency testing records from the Wisconsin State Laboratory of Hygiene (WSLH) (2017 event 1) revealed the laboratory failed to have documentation of the review of the following results: 2017 WSLH event 1 2017 API event 2 2. The laboratory was asked to provide

	documentation of the identified results being reviewed. No documentation was provided. 3. An interview with the medical assistant on 03/13/2018 at 1330 hours in the break room - after her review of the records- confirmed the findings.
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 review of the laboratory's records, and staff interview, it was revealed the laboratory failed to provide overall quality testing. The findings were: 1. The laboratory failed to have documentation of following its policy for repeating CBC (complete blood count) tests (refer to D5401). 2. The laboratory failed to have documentation of resolving flags on CBC (complete blood count) results prior to reporting the results to the provider (refer to D5403). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 03/21/2016 3. The laboratory failed to have documentation of performing calibrations on the Medonic M-series hematology analyzer at least every six months as required by the manufacturer (refer to D5437). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 03/21/2016 4. The laboratory failed to have documentation of verifying new lots of controls prior to placing the controls into use (refer to D5469).
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, review of patient test results from September 2017 to February 2018, and staff interview, it was revealed the laboratory failed to have documentation of following its policy for repeating CBC (complete blood count) tests. The findings were: 1. A review of the laboratory's policy titled "Policy for Repeating CBC Tests" (approved by the laboratory director on 03/05 /2001) revealed: "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when patient results are outside the following range: RBC less than 4.00 or greater than 6.00 million WBC less than 4.00 or greater than 11.00 thousand HCT less than 30% or greater than 50% HGB less than 10 or greater than 18 mg/% PLT less than 150 or greater than 450 thousand 2. A review of patient test records from September 2017 to February 2018 revealed the following patient results which met the laboratory's criteria for repeat testing: Date ID Test(s) 09 /11 12121940 WBC: 3.90 09/21 11131934 RBC: 3..36 09/25 03041933 RBC: 2.80 HGB: 8.8 HCT: 25.5 PLT: 75 09/28 04021931 RBC: 3.75 PLT: 145 10/28 07281945

	PLT: 148 11/28 02241950 RBC: 3.65 HGB: 9.9 HCT: 28.0 12/19 09231933 WBC: 2.4 RBC: 1.90 HGB: 7.1 HCT: 20.7 PLT: 140 01/09 07181959 WBC: 11.8 02/21 03301941 RBC: 3.86 3. The laboratory was asked to provide documentation of repeating the identified tests as required by its policy. No documentation was provided. 4. An interview with the medical assistant on 03/13/2018 at 1335 hours in the break room - after her review of the records- confirmed the findings. Key WBC- white blood cell RBC- red blood cell HGB- hemoglobin HCT- hematocrit PLT- platelet
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Medonic M-series hematology analyzer, review of patient test records from September 2017 to February 2018, and staff interview, it was revealed the laboratory failed to have documentation of resolving flags on CBC (complete blood count) results prior to reporting. The findings were: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer (Art no 1504236, March 2009) under the section titled "System Information Flags" revealed the manufacturer identified the following flags and corrective actions to perform: a) BD Description: The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. b) NM Description: There was no mode in the WBC distribution between the LYM-L and GRAN-H settings. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. c) OM Description: There was only one mode in the WBC distribution between the LYM-L and GRAN-H settings. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. d) TM Description: There were more than two modes in the WBC distribution between the LYM-L and GRAN-H settings. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. 2. A review of patient test records from September 2017 to

	January 2018 identified the following patient results with flags which were reported to the provider: Date ID Flag 09/05 08181926 BD 09/19 03301941 BD 09/25 08071922 OM 09/26 06221931 OM 10/4 05041928 BD 11/29 01061931 TM 11/29 08201948 OM 11/30 05151954 OM 12/04 10031940 BD 01/10 05101944 OM 01/19 06021933 OM 01/26 04061958 BD (first run) OM (second run) 3. The laboratory was asked to provide documentation of performing corrective actions prior to reporting out the identified patient results. No documentation was provided. 4. An interview the the medical assistant on 03/13/2018 at 1340 hours in the break room - after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 03/21/2016
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 review of the manufacturer's instructions for the Medonic M-series hematology analyzer, review of the laboratory's calibration records from 2015, 2016, and 2017, and staff interview, it was revealed failed to have documentation performing calibrations every six months as required. The findings were: 1. A review of the manufacturer's instructions of the Medonic M-series hematology analyzer (Art no 1504236, March 2009) under the section titled "Section 7: Calibration" revealed: "It is recommended to calibrate the instrument every 6 months." 2. A review of the laboratory's calibration records from 2015, 2016 and 2017 revealed the laboratory had documentation of performing calibrations the following times: 06/2015 04/2016 (10 months later) 07/2016 (3 months later) 03/2017 (8 months later) 04/2017 (1 month later) 10/2017 (6 months later) 3. The laboratory was asked to provide documentation of performing calibrations every six months as required. No documentation was provided. 4. An interview with the medical assistant on 03/13/2018 at 1335 hours in the break room - after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 03/21/2016.
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 review of the laboratory's quality control records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of verifying new lots of quality control material prior to placing the controls into use. The findings were: 1. A review of the laboratory's CDS Boule Con-Diff quality control records from 2016 and 2017 revealed the laboratory failed to have documentation of verifying 5 of 8 lots of control material used by the laboratory. The lots without documentation of verification were: a) Lot: 21608 In use October 2016 to December 2016 b) Lot: 21611 In use January 2017 to March 2017 c) Lot: 21702 In use April 2017 to June 2017 d) Lot: 21705 In use July 2017 to September 2017 e) Lot: 21708 In use October 2017 to December 2017 2. Further review of the laboratory's CDS Boule Con-Diff quality control records from 2016 and 2017 revealed the laboratory attempted to verify two lots of control material, however, the results of the controls runs were outside the manufacturer's acceptable ranges. Examples of this are: a) Lot: 21602 In use March 2016 to May 2016 Low Control Analyte Range Result WBC 3.2 - 3.8 3.0 WBC 3.2 - 3.8 3.1 WBC 3.2 - 3.8 3.1 WBC 3.2 - 3.8 3.1 WBC 3.2 - 3.8 4.5 RBC 2.01 - 2.25 2.99 HGB 5.2 - 5.8 7.7 HCT 12.0 -17.0 20.1 PLT 69 - 99 111 Normal Control Analyte Range Result HGB 11.3 - 12.1 12.3 HGB 11.3 - 12.1 12.3 HGB 11.3 - 12.1 11.2 WBC 7.8 - 9.0 7.2 WBC 7.8 - 9.0 11.0 RBC 3.79 - 4.15 5.34 HGB 11.3 - 12.1 15.2 HCT 29.4 - 35.4 42.9 High Control Analyte Range Result HGB 14.5 - 15.5 15.6 HGB 14.5 - 15.5 15.7 WBC 18.6 - 22.2 17.7 WBC 18.6 - 22.2 24.5 RBC 4.47 - 4.91 6.08 HGB 14.5 - 15.5 19.2 HCT 38.6 - 45.6 53.9 b) Lot: 21605 In use June 2016 to September 2016 Low Control Analyte Range Result RBC 2.01 - 2.25 1.96 HGB 5.1 - 5.7 5.0 WBC 3.1 - 3.7 3.8 RBC 2.01 - 2.25 2.59 HGB 5.1 - 5.7 6.6 HCT 12.9 - 16.9 17.1 PLT 68 - 98 102 WBC 3.1 - 3.7 3.8 RBC 2.01 - 2.25 2.67 HGB 5.1 - 5.7 6.7 HCT 12.9 - 16.9 17.7 WBC 3.1 - 3.7 3.0 RBC 2.01 - 2.25 2.41 HGB 5.1 - 5.7 6.1 RBC 2.01 - 2.25 2.33 WBC 3.1 - 3.7 3.8 RBC 2.01 - 2.25 2.86 HGB 5.1 - 5.7 7.2 HCT 12.9 - 16.9 18.9 Normal Control Analyte Range Result WBC 7.8 - 9.0 9.8 RBC 3.76 - 4.12 4.86 HGB 11.1 - 11.9 14.2 HCT 29.2 - 35.2 38.8 PLT 203 - 263 271 RBC 3.76 - 4.12 4.45 HGB 11.1 - 11.9 13.1 HCT 29.2 - 35.2 35.5 RBC 3.76 - 4.12 4.19 HGB 11.1 - 11.9 12.1 RBC 3.76 - 4.12 4.16 HGB 11.1 - 11.9 12.3 HGB 11.1 - 11.9 12.1 RBC 3.76 - 4.12 4.26 HGB 11.1 - 11.9 12.6 High Control Analyte Range Result RBC 4.50 - 4.94 5.40 HGB 14.4 - 15.4 16.8 HCT 38.6 - 45.6 47.2 RBC 4.50 - 4.94 5.07 HGB 14.4 - 15.4 16.3 HGB 14.4 - 15.4 15.5 RBC 4.50 - 4.94 5.04 HGB 14.4 - 15.4 16.1 RBC 4.50 - 4.94 5.06 HGB 14.4 - 15.4 16.3 WBC 18.7 - 22.3 18.1 3. The laboratory was asked to provide documentation of verifying new lots of controls prior to use. No documentation was provided. 4. An interview with the medical assistant on 03/08/2018 at 1340 hours in the break room - after her review of the records- confirmed the findings. Key WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result

	indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test records from June 2017 to December 2017, and staff interview, it was revealed the laboratory failed to have documentation of the notification of critical values. The findings were: 1. A review of the laboratory's policy titled "Reporting Critical Values" (approved by the laboratory director on 04/28/2016) revealed: "It is the policy of the laboratory to document the reporting of all Critical Values. these results must be verified by repeat analysis prior to reporting and this must be document (sic) as follows: - who was notified - when was the person notified (date and time) - by whom was the person notified - what test and result is being reported 2. A review of the laboratory's policy titled "Panic Values" (approved by the laboratory director on 03/05/2001) revealed the laboratory defined its critical values as: WBC under 2.0 or greater than 20.0 HGB under 7.5 or greater than 18 HCT under 25 or greater than 55% PLT under 50 or greater than 800 3. A review of patient test records from June 2017 to December 2017 identified the following patient results which met the laboratory's criteria as a critical value: Date ID Test 06/27 08291984 WBC: 21.2 12/19 09231933 HGB: 7.1 HCT: 20.7 4. The laboratory was asked to provide documentation of the notification of the identified critical values as required by its policy. No documentation was provided. 5. An interview with the medical assistant on 03/13/2018 at 1345 hours in the break room revealed she was unaware of the laboratory's policy to document the notification of critical values. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 03/21/2016 Key WBC- white blood cell HGB - hemoglobin HCT- hematocrit PLT- platelet
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 review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. The findings were: 1. The laboratory director failed to ensure proficiency testing was performed as required (refer to D6016). 2. The laboratory director failed to ensure proficiency testing results were reviewed (refer to D6018). 3. The laboratory director failed to ensure a quality control program was established and followed (refer to D6020). 4. The laboratory director failed to ensure the laboratory's quality assurance plan was followed (refer to D6021).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the

	tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by:
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and staff interview, it was revealed the laboratory director failed to ensure proficiency testing samples were tested as required (refer to D2007 and D2009).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and staff interview, it was revealed the laboratory director failed to ensure proficiency testing results were reviewed (refer to D5211).
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 review of the laboratory's quality control records and staff interview, it was

	revealed the laboratory director failed to ensure a quality control program was developed and followed (refer to D5469).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance plan, the review of the laboratory's quality assurance records from 2016 and 2017, and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assurance plan was followed. The findings were: 1. A review of the laboratory's quality assurance plan (approved by the laboratory director on 03/05/2001) revealed the laboratory was to perform quality assurance reviews monthly which were to be reviewed, signed and dated by the laboratory director. 2. A review of laboratory's quality assurance records from 2016 and 2017 revealed the laboratory failed to have documentation of the laboratory director reviewing, signing and dating 24 of 24 monthly reports. 20 of the 24 reports had not been printed as of the date of the survey. 3. The laboratory was asked to provide documentation of the laboratory director review, signing, and dating the quality assurance records. No documentation was provided. 4. An interview with the medical assistant on 03/08/2018 at 1330 hours in the break room - after her review of the records- confirmed the findings.
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 the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of technical consultant performing a competency assessment on 1 of 1 testing personnel who required one in 2017. The findings were: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing an annual competency assessment in 2017 for testing personnel number 1 (as listed on Form CMS 209). 2. The laboratory was asked to provide documentation of a competency assessment being performed on testing personnel number 1 in 2017. No documentation was provided. 3. An interview with the medical assistant on 03/13 /2018 at 1340 hours in the break room - after her review of the records- confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii)

	Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have complete documentation of training for 2 of 3 testing personnel. The finding were: 1. A review of the laboratory's personnel records revealed the laboratory failed to have complete documentation of training for 2 of 3 testing personnel who performed moderate complexity testing. They were (as listed on Form CMS 209): Testing personnel number 2 Testing personnel number 3 Note: The records for each of the identified testing personnel contained a 'New Hire Training" record, however the records were not signed by the trainer to attest that training had indeed occur. 2. The laboratory was asked to provide documentation of training. No documentation was provided. 3. An interview with the medical assistant on 03/13 /2018 at 1340 hours in the break room - after her review of the records- confirmed the findings.