Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0888296	08/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab did not check the CRP test for accuracy (proficiency check) at least two times each year. Findings: 1. The lab performs CRP testing but is not checking the accuracy of the CRP test at least two times a year; 2. This was confirmed during interview with lab staff at 3:00 pm on the day of survey.
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 record review and interview with laboratory (lab) staff, the lab did not rotate proficiency testing duties among all testing personnel performing lab testing. Findings: 1. Testing person A is independently testing patient samples and reporting their test results for complete blood counts (CBC); 2. The proficiency test provider ships three separate challenges each year for the lab to test and report to the provider to evaluate for accuracy; 3. The proficiency test provider records include attestation statements for the testing person to sign and date to identify their responsibility for

	performing proficiency tests in the same manner as patient specimens; 4. The surveyor was informed by lab staff during interview on the afternoon of the day of survey, that testing person A was testing patient samples for CBC and was not rotated through proficiency testing challenges; and 5. The attestation records for the first and second event of 2018 identify testing person B as person responsible for performing proficiency tests for CBC challenges, even though testing person A was also trained and responsible for performing patient CBC tests.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the lab did not document that blood lead quality control testing was performed on 5/13/18, 12/20/17, 9/3/17 and 7/1 /17 for either of the two quality control reagents. Findings: 1. Under the Code of Maryland Regulations 10.10.06.05 Quality Control - General. A. Primary Standard. A licensee operating under a permit shall ensure that the laboratory establishes and follows written quality control procedures for monitoring and evaluating the quality of the analytic phase of the testing process for each testing method and procedure to assure the accuracy and reliability of patient test results and reports; 2. The lab reports the results of the two levels of quality control reagent on the "Lead Testing System Data Sheet"; 3. During interview at 2:00 pm on the day of survey, staff stated that quality control tests are performed each day of patient testing; and 4. The results of the two levels of quality control tests were not reported on the "Lead Testing System Data Sheet" on 5/13/18, 12/20/17, 9/3/17 and 7/1/17.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab did not have documentation that testing person A was provided chemical hygiene and biological hazard training. Findings: 1. Testing person A is performing laboratory tests as stated by staff during interview in the afternoon on the day of survey and that chemical hygiene and biological hazard training was not documented; and 2. There was no record that this training was conducted.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by:

	Based on record review and interview with laboratory (lab) staff, the lab did not report the date and time specimens are received in the lab. Findings: 1. The final report did not include the date and time the patient specimen was received by the lab for ten of ten final reports reviewed, since the lab receives specimens from other offsite offices within the practice, as reported by staff during interview (at 1:00 pm) on the day of survey, the date of receipt is important to determine acceptability of a patient sample and ensure tests were not performed on specimens that were too old, improperly stored and of substandard quality; and 2. There is a place to report the received date and time on the final report, but the data was missing.
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 record review and interview with lab staff, the lab did not have written procedures for interpreting HIV test reactions for reactive antibody only results and antigen reactive only results. Findings: 1. The laboratory performs moderate complexity HIV testing, as it performs the test on whole venous blood, thus making the test complexity moderate. The manufacturer instructions include results for antibody reactive only results and antigen reactive only results, but the labs written procedures did not have instructions for interpretation of these reactions; and 2. This was confirmed during interview of lab staff at noon on the day of survey.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the written procedure and interview with laboratory (lab) staff, the written procedure for a discontinued chlamydia test procedure that is no longer in use was still part of the labs standard operating procedure manual. The procedure was not

	labeled as retired and this was confirmed during interview with lab staff on the day of survey.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on record review and interview with laboratory (lab) staff, the lab did not follow manufacturers instructions to ensure specimen integrity in order to conduct accurate and reliable patient testing. Findings: 1. Urine culture and throat culture specimens must be stored under proper conditions and cultured within the time limits established by the labs written procedure in order to provide accurate and reliable results, in addition hematology and chemistry samples must also be stored and tested within the labs established time limits to ensure accurate and reliable testing; 2. Patient A had a throat culture collected on 8/15/18, the test date is 8/19/18. The manufacturer of the selective strep agar requires a throat culture using selective strep agar (as performed in the lab) to be freshly collected for culture and states that if a delay of "1-2 hours is unavoidable, transport medium such as Stuart's or Amies should be used. Every effort should be made at prompt specimen inoculation. Extended delays in processing permit overgrowth of potential pathogens by normal respiratory flora." This patients test was interpreted on 8/19/18. There is a two day delay between collection and culture for this patients test and the result was reported as negative for beta strep; 3. Patient B had a Complete Blood Count (CBC) collected on 4/12/18 and the test date is 4/17/18, the manufacturer of the CBC analyzer states that venous whole blood specimens be tested within 6 hours of collection for most accurate results. This specimen exceeded the 6 hour time limitation for specimen collection; 4. Patient C had a Complete Blood Count (CBC) collected on 8/24/18 and the test date is 8/27/18, the manufacturer of the CBC analyzer states that venous whole blood specimens be tested within 6 hours of collection for most accurate results. This specimen exceeded the 6 hour time limitation for specimen collection; 5. Patient D had a Complete Blood Count (CBC) collected on 3/8/18 at 5:24 pm and the test date is 3/9/18 at 3:16 pm, the manufacturer of the CBC analyzer states that venous whole blood specimens be tested within 6 hours of collection for most accurate results. This specimen exceeded the 6 hour time limitation for specimen collection; and 6. The lab did not have a quality assurance procedure to identify delays in testing and ensure that patient samples are stored and tested within acceptable time limits. 07149 B. Based on review of the hematology Levy-Jennings (L-J) quality control (QC) printouts and interview with the laboratory supervisor, the laboratory did not test three levels of QC materials each day of testing on the Medonic hematology analyzer as required by the manufacturer. Findings: 1. Review of the hematology L-J QC printouts from April and May 2018 showed that QC had not been tested on April 28 to May 11, 2018. The laboratory is open Monday through Saturday. QC results were missing from 04/28, 04 /30, 05/01-05, and 05/06-11/18 for a total of 13 days. 2. The laboratory supervisor stated that the laboratory was having problems with the QC data transferring to the LIS. The laboratory supervisor was able to retrieve hard copies of the QC results for 05/06 and 05/08-11/2018 but could not locate the other missing results. 3. During the survey on 08/29/2018 at 3:30 PM the laboratory supervisor confirmed that the

	hematology QC records did not include data from 05/06 and 05/08-11/2018 showing that QC materials were not tested each day of testing.
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 record review and interview with laboratory (lab) staff, the laboratory did not ensure that the room temperature range met requirements for performing the RPR test. Findings: 1. The labs room temp requirements for performing the RPR test is between 23 to 29 degrees Centigrade (C) as stated in the labs written procedure. The lab was reporting the temperature in Fahrenheit (F) with a range of 64 to 79 degrees F; 2. On May 11 and 18, 2018 and February 23, 2018 and January 5, 2018 quality control testing was performed for the RPR test and the temperatures were documented as 64 degrees F on each of these days. 64 F converts to 18 degrees C. 18 C does not meet the labs room temperature criteria for acceptability to perform the RPR test; and 3. This was confirmed during interview of lab staff at noon on the day of survey.
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 and interview with laboratory staff, the lab did not ensure reagents were not used past expiration. Findings: 1. The lab refrigerator contained a box of Calibration verification reagent for creat/alb lot 76AB17515 with an expiration date of 2017-01-02 and an AIA pack diluent concentrate for lot H380037 with an expiration date of 2018-2-28; 2. These boxes were not labeled for research use only and not for patient testing; and 3. Lab staff stated that the reagents were not used for patient testing, but had not been positively labeled to not use for patient testing. This was confirmed during interview with lab staff at 10:00 am on the day of survey; 4. The lab performs blood lead testing and reports results on the "Lead Testing System Data Sheet"; 5. The blood lead test for lot number 1611 expiring on 5/30/18 was used for patient testing on 5/31/18 as reported on the test record; and 6. The test record was reviewed with lab staff during interview on the day of survey to confirm that the record show the use of an expired test kit for patient testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on record review and interview with laboratory (lab) staff, the lab did not conduct quality control testing for the HIV test as required by the manufacturer. Findings: 1. The lab is performing moderate complexity HIV testing as it uses patient venous whole blood for testing; 2. The manufacturer package insert instructs the lab to perform monthly liquid or external quality control checks; 3. The labs written procedure states that external quality control checks are only performed for each new lot of test kits. The lab did not follow manufacturer instructions and test quality control reagents monthly; and 4. This was confirmed during interview with lab staff at noon on the day of survey. B. Based on record review and interview with laboratory (lab) staff, the lab did not conduct quality control testing for the serum HCG test as required by the manufacturer. Findings: 1. The lab performs moderate complexity HCG testing as it uses patient serum for testing; 2. The manufacturer states in the package insert for the serum HCG test to perform monthly liquid or external quality control checks; 3. The labs written procedure states that external quality control checks are only performed for each new lot of test reagents; and 4. This was confirmed during interview with lab staff at noon on the day of survey.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on review of the hematology Levy-Jennings (L-J) quality control (QC) printouts and interview with the laboratory supervisor, the laboratory did not document corrective action when the QC results did not transfer to the laboratory information system (LIS). Findings: 1. Review of the hematology L-J QC printouts from April and May 2018 showed that QC had not been tested on April 28 to May 11, 2018. The laboratory is open Monday through Saturday. QC results were missing from 04/28, 04/30, 05/01-05, and 05/06-11/18 for a total of 13 days. 2. The laboratory supervisor stated that the laboratory was having problems with the QC data transferring to the LIS. The laboratory supervisor was able to retrieve hard copies of the QC results for 05/06 and 05/08-11/2018 but could not locate the other missing

	results. 3. During the survey on 08/29/2018 at 3:30 PM the laboratory supervisor confirmed that the hematology QC data was missing and that the laboratory had not written up corrective actions taken to ensure that the QC data continued to transfer to the LIS in the future. B. Based on review of the chemistry QC printouts and interview with the laboratory supervisor, the laboratory did not document corrective actions when the aspartate transaminase (AST) and alanine transaminase (ALT) QC results had shifted below the mean by more than 1 standard deviation (SD) showing a low bias. Findings: 1. The QC printouts for May 2017, April and May 2018 were reviewed. The QC materials used during May 2017 expired on 02/28/2018. The QC materials used during April and May expired on 05/31/2021. 2. The QC records show that the AST mean listed for May 2017, Level 1 was 47 and the calculated mean was 41.56. The reference range for AST Level 1 was 38-56. The QC results for AST, Level 1 had shifted below the mean by more than 1 standard deviation (SD) showing a low bias. The QC records show that the AST mean listed for April and May 2018, Level 1 was 44 and the calculated mean was 39.20 and 39.79 respectively. The reference range for AST Level 1 was 38.2-49.8. The QC results for AST, Level 1 had shifted below the mean by more than 1 SD showing a low bias. 3. The QC records show that the AST mean listed for May 2017, Level 2 was 204 and the calculated mean was 185.94. The reference range for AST Level 2 was 163-245. The QC results for AST, Level 2 had shifted below the mean by more than 1 SD showing a low bias. The QC records show that the AST mean listed for April and May 2018, Level 2 was 44 and the calculated mean was 164.70 and 165.63 respectively. The reference range for AST Level 2 was 159.40-208.60. The QC results for AST, Level 2 had shifted below the mean by more than 1 SD showing a low bias. 4. The QC records show that the ALT mean listed for May 2017, Level 1 was 40 and the calculated mean was 33.38. The reference range for ALT Level 1 was 32-48. The QC results for ALT, Level 1 had shifted below the mean by more than 1 SD showing a low bias. The QC records show that the ALT mean listed for April and May 2018, Level 1 was 41 and the calculated mean was 36.40 and 37.16 respectively. The reference range for ALT Level 1 was 35.4-46.6. The QC results for ALT, Level 1 had shifted below the mean by more than 1 SD showing a low bias. 5. The QC records show that the ALT mean listed for May 2017, Level 2 was 116 and the calculated mean was 104.69. The reference range for ALT Level 2 was 93-162. The QC results for ALT, Level 2 had shifted below the mean by more than 1 SD showing a low bias. The QC records show that the ALT mean listed for April and May 2018, Level 2 was 110 and the calculated mean was 98.20 and 98.89 respectively. The reference range for ALT Level 2 was 95.20-124.80. The QC results for ALT, Level 2 had shifted below the mean by more than 1 SD showing a low bias. 6. When interviewed on 08/29/18 at 3:30 PM the laboratory supervisor confirmed that Level 1 and 2 for the AST and ALT had shifted 1 SD and no corrective actions had been taken to correct the mean.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by:

	Based on review of the hematology instrument printouts and interview with the laboratory supervisor, the laboratory's record system did not include the identity of the personnel who performed the hematology testing. Findings: 1. The Personnel Laboratory Report (CLIA) (CMS-209) lists two testing persons. The laboratory supervisor stated that he usually works the evening shift and performs all the chemistry testing. Occasionally he will perform the testing on the hematology analyzer if specimens are left over from the day shift. 2. Review of the hematology instrument printouts from 2017 and 2018 showed that the only initials listed were TP. The laboratory supervisor confirmed that the initials TP were not the initials of the day shift testing person. 3. During the survey on 08/29/18 at 3:00 PM the laboratory supervisor confirmed that the hematology instrument printouts from 2017 and 2018 did not have the initials of the person who performed the testing.