Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1009254	03/06/2019
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for storage of Rapid Strep A Consult Diagnostics test kits. The findings were: 1. Surveyor observation at 09:10 hours during a tour of the facility found 1 box of unopened Rapid Strep A Consult Diagnostics test kits (lot #STA8080074, expiration date: 8-31-2020) located in the storage closet. No means of monitoring the temperature of the room was observed. 2. Review of the manufacturer's instructions located on the outside of the kit packing stated the storage temperature of the kit was, "36-86 degrees Fahrenheit or 2-30 degrees Celsius." 3. Interview of testing personnel #2 (as listed on Form CMS-209) on March 6, 2019 at 09:15 hours in the patient exam room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 laboratory policy, review of proficiency testing records, and confirmed in interview of facility personnel, the laboratory failed to retain proficiency testing records for 2 years. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing" approved by the laboratory director on May 20, 2013, stated, " ...All records and reports will be maintained for two years." 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2017 (events 1, 2, and 3) and 2018 (events 1, 2, and 3) revealed the laboratory failed to retain the instrument printouts for 2017 (event 2). 3. Review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2017 (events 1, 2, and 3) and 2018 (events 1, 2, and 3) revealed the laboratory failed to retain the Comparative Evaluation for 2017 (event 2). 4. The facility attempted to retrieve the records from the analyzer but the records were no longer available in the instrument. The laboratory was unable to successfully retrieve the instrument print outs on March 6, 2019. 5. Interview with the technical consultant on March 6, 2019 at 10:25 hours in the patient exam room confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing results from 2017 and 2018, and confirmed in interview of facility personnel, the laboratory failed to have documentation of evaluating proficiency testing results returned by the proficiency testing agency as "Not Graded." The findings were: 1. This is a repeat deficiency from the survey dated January 3, 2017. 2. A review of the laboratory's API proficiency testing records from 2017 (events 1, 2, and 3) and 2018 (events 1, 2, and 3) revealed the following results were returned as "Not Graded (No Consensus)": 2017 - Hematology (event 2) Sample ID: HEM-07 Reported Result (Monocytes): 13.7 Grade: "Not Graded (No Consensus) 2017 - Hematology (event 2) Sample ID: HEM-10 Report Result (Monocytes): 12.1 Grade: "Not Graded (No Consensus) 3. An interview with the technical consultant on March 6, 2019 at 10:30 hours in the patient exam room confirmed the findings. Key: HEM - hematology
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 surveyor observation, review of the manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to have documentation of monitoring the room temperature where laboratory supplies were stored. The findings were: 1. Surveyor observation made on March 6, 2019 at 09:10 hours during the initial tour of the facility revealed no means to monitor the room temperature of the facility's storage closet. 2. Direct observation of supplies stored in the facility's storage closet revealed the following items: a. BD red top Vacutainer tubes (lot 8226915): quantity of 30 tubes b. BD yellow top Vacutainer tubes (lot 8278849): quantity of 25 tubes c. Boule Cleaning Kit (lot 7508): quantity of 1 opened kit 3. A review of the manufacturer's instructions located on package labeling for the BD Vacutainer blood collection tubes revealed the manufacturer required the tubes to be stored at a temperature range of "4 - 25C". 4. A review of the manufacturer's instructions for Boule Cleaning Kit located on package labeling revealed the manufacturer required the kit to be stored at "15-30 degrees Celsius." 5. Interview with testing person #2 (as listed on Form CMS-209) on March 6, 2019 at 09:15 hours in the patient exam room confirmed the findings. Key BD - Becton Dickinson CMS - Centers for Medicare and Medicaid Services
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 laboratory policy, review of manufacturer's instructions, review of maintenance records, and confirmed in interview of facility personnel, the laboratory failed to ensure reagents were not used after their expiration date. The findings were: 1. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on May 20, 2003, it stated, " ...Maintenance of each piece of laboratory instrumentation shall be in accordance with the manufacturer's recommendations ..." 2. Review of the manufacturer's instructions for the Boule Cleaning Kit (11452-1, 2009-03-10) under, "Contents" it stated, "The contents can be used for three full and complete cleaning cycles. Remaining cleaning solution should be disposed of." 3. Review of maintenance records from January 2018 to March 2019 revealed the laboratory performed maintenance on the Medonic hematology analyzer using Boule Cleaning Kit opened on 02-29-2018 as follows: April 24, 2018 June 29, 2018 November 2, 2018 March 5, 2019 4. The maintenance procedure performed on March 5, 2019 was performed using expired reagents. 5. An interview with testing personnel #1 (as listed on Form CMS-209) on March 6, 2019 at 09:30 hours in the patient exam room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 laboratory policy, review of manufacturer's instructions, review of calibration records, and confirmed in interview of facility personnel, the laboratory failed to perform complete calibration procedures. The findings were: 1. Review of laboratory policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on May 20, 2003, it stated, "Calibration of all laboratory instruments will be every six months, every time there is a complete change in lot numbers, or when controls don't give desired results. Calibrations have to be done more frequently if the manufacturer indicates it. 2. Review of the manufacturer's instructions for the Medonic M-series hematology analyzer (Article No. 1504248, May 2009) under, "Section 7: Calibration" it stated, "This section describes the step-by-step procedure for calibration of the Medonic M-Series." 3. Review of the laboratory's calibration records from January 2017 to December 2018 revealed the laboratory perform instrument calibrations as follows: January 24, 2017 April 14, 2017 July 25, 2017 October 11, 2017 January 17, 2018 April 25, 2018 August 1, 2018 December 31, 2018 4. Review of post-calibration records revealed that calibrations for the following dates were incomplete: October 11, 2017 The laboratory failed to calibrate all analytes: MCV (previous calibration 07/25/2017) PLT (previous calibration 07/25/2017) MPV (previous calibration 07/25/2017) HGB (previous calibration 07/25/2017) WBC (previous calibration 07/25/2017) January 17, 2018 The laboratory failed to calibrate all analytes: MCV (previous calibration 07/25/2017) PLT (previous calibration 07/25/2017) MPV (previous calibration 07/25/2017) HGB (previous calibration 07/25/2017) WBC (previous calibration 07/25/2017) December 31, 2018 The laboratory failed to calibrate all analytes: MCV (previous calibration 08/01/2018) MPV (previous calibration 08/01/2018) HGB (previous calibration 08/01/2018) WBC (previous calibration 08/02/2018) 5. Interview of the technical consultant on March 6, 2019 at 11:30 hours in the patient exam room confirmed the findings. He agreed the calibrations were incomplete.
D6012	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) The test methodologies selected have the capability of providing the quality of results required for patient care;

	This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the Medonic Patient Sample Summary Report, review of patient final reports, and confirmed in interview of facility personnel, the laboratory director failed to ensure the laboratory's methodologies provide quality results. The findings were: 1. Review of the laboratory's policy titled, "Corrective Action for an Error in Test Result Report" approved by the laboratory director on February 27, 2013 stated, "The following steps are to be taken when an error has been detected in reporting patient results." It went on to state: -Verify the error. -Notify the ordering Physician. -Make the correction, but do not "white out" or otherwise erase the erroneous result. You may make one line through, or "cross-out" the error. Be sure to keep both the original report and corrected one. -Keep documentation in the lab on what happened. -Keep records for at least 2 years. 2. Random review of 5 patient final reports revealed that for the patient that was performed as Sequence #2281 on February 5, 2019 at 13:18 hours, the laboratory resulted: WBC = 6.4 LYM = 1.0 MID = 0.3 GRAN = 5.1 LYM% = 15.6 MID% = 4.1 GRA% = 80.3 RBC = 4.06 HGB = 11.5 HCT = 35.3 MCV = 86.8 MCH = 28.4 MCHC = 32.7 RDW% = 13. PLT = 138 (the original result was marked out and "155" was written in) MPV = 8.6 3. Review of the Medonic Patient Sample Summary Report from February 1, 2019 to February 28, 2019 revealed that due to sample flagging, the patient sample was repeated with the following results: WBC = 6.5 LYM = 0.8 MID = 1.3 GRAN = 4.4 LYM% = 13.7 MID% = 17.4 GRA% = 68.9 RBC = 3.97 HGB = 11.5 HCT = 34.4 MCV = 86.5 MCH = 28.9 MCHC = 33.4 RDW% = 13.1 PLT = 155 MPV = 8.6 4. The laboratory failed to follow its own policy to document why the report was amended. 5. Interview with testing personnel #2 (as listed on Form CMS-209) on March 6, 2019 at 11:50 hours in the laboratory confirmed the findings. When asked why the report had been amended, she revealed that she could not remember specifically why this particular sample's report had been amended, but if the provider looked at the compared results and felt it may be erroneous, it would be amended. She went on to state that as an example, "If she realized there was a clot in the sample, she would remove the clot and then retest the sample." Key: CMS - Centers for Medicare and Medicaid Services WBC - white blood cell LYM - lymphocyte GRA -granulocyte RBC - red blood cell HCT - hematocrit HGB - hemoglobin MCV - mean cell volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration RDW - red cell distribution width PLT - platelet MPV - mean platelet volume
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, and confirmed in interview of facility personnel, the technical consultant failed to perform competency assessments on each testing person at least twice annually during their first year of patient testing. The findings were: 1. Review of the laboratory's personnel records revealed that testing person #2 (as listed on Form CMS-209) had a laboratory start date of July 8, 2016. 2. Further review of the personnel records for testing person #2 (as listed on Form CMS-209) revealed there were not two competency assessments performed during her first year of patient testing. 3. The testing person had a competency

	assessment performed on January 15, 2019, 3 years, 6 months, and 7 days after her initial start date). 4. An interview with the technical consultant on March 6, 2019 at 09: 45 hours in the patient exam room confirmed the findings. He confirmed that he could not locate the records or copies of the records. Key: CMS - Centers for Medicare and Medicaid Services
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, and confirmed in interview of facility personnel, the technical consultant failed to perform annual competency assessments on each testing person. The findings were: 1. Review of the laboratory's personnel records revealed that testing person #2 (as listed on Form CMS-209) had a laboratory start date of July 8, 2016. 2. Further review of the personnel records for testing person #2 (as listed on Form CMS-209) revealed there was not an annual competency assessment available for review that was performed in 2018. 3. An interview with the technical consultant on March 6, 2019 at 09:45 hours in the patient exam room confirmed the findings. He confirmed that he could not locate the records or copies of the records. Key: CMS - Centers for Medicare and Medicaid Services