Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0968944	08/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mycare Medical Of Texas, Pllc	1002 West Sam Houston Suite 4, Pharr, 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 DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; 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.
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: A. Based on review of laboratory policy, review of manufacturer's instructions, review of patient reports, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy to send out patient samples with flags on the CBC for confirmation. 1. Review of the laboratory's policy titled, "Actions Protocol for WBC Differential Flags" approved by the laboratory director on March 21, 2018 stated, " ... If the flags persist then send an EDTA Tube that may transporting for testing at a Reference Laboratory." 2. Review of the manufacturer's instructions for the Medonic M-Series hematology system analyzer (Article no: 1504248, May 2009) stated,

	""Abnormalities: Follow your laboratory's protocol for verification on all samples with anomalies and/or abnormal distributions signaled by the instrument. Pathological cells may vary in their stability toward lysing of their ctyoplasmic membranes compared to normal cells, which may cause aberrations in the automated analysis. This also applies to the presence of normal non-pathological cells that have been subjected to chemotherapy or other treatments." And, BD - WBC DIFF: high interference between populations: Blood sample too old or pathological sample. Action: Follow laboratory's protocol for verification of results. OM - WBC DIFF: only one WBC population found; slide review advised. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. TM - WBC DIFF: too many WBC populations found; slide review advised. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. 3. Random review of patient results revealed the following patient results were provided to the healthcare provider prior to the flags being resolved: Date: 08/12/2018 Sequence # 4792 Flag: OM Date: 08/20/2018 Sequence # 5061 Flag: OM Date: 08/05 /2018 Sequence # 4539 Flag: BD 4. The CBC results were not sent out to a referral laboratory for confirmation as directed by the laboratory's own policy. 5. An interview with testing personnel one (as listed on Form CMS-209) on 08/27/2018 at 16:30 hours in the laboratory confirmed the findings, Key: CMS - Centers for Medicare and Medicaid Services CBC - complete blood count WBC - white blood cell EDTA - ehtylenediamenetetraacetic acid B. Based on review of laboratory policy, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy to ensure each testing person signed and dated their review of the laboratory procedure manual. The findings were: 1. Review of the laboratory's policy titled, "Procedure Manual Documentation" approved by the laboratory director on June 22, 2018, stated, "We the undersigned acknowledge that we have reviewed the material in this Procedure Manual and are knowledgeable of its deletions, revisions, additions and contents that pertain to our job responsibilities." 2. Review of the policy signature form revealed it was not signed by testing personnel number seven (as listed on Form CMS-209). 3. An interview with testing personnel one (as listed on Form CMS-209) on 08/27/2018 at 15:00 hours in the office confirmed the findings. She revealed the employee only worked Saturdays (PRN) and had left him reminders, but he forgot to perform the task. Key: CMS - Centers for Medicare and Medicaid Services
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's maintenance records, and confirmed in interview, the laboratory failed to provide documentation of performing daily maintenance on the Medonic hematology analyzer in December 2017. The findings were: 1. Review of the manufacturer's instructions for the Medonic M series hematology analyzer (Art. no 1504483, November 2016), under "Daily Cleaning" it stated, "The majority of the Medonic M-series system's cleaning procedures are automated to keep routine cleaning to an absolute minimum, increase the longevity of the analyzer and decreases maintenance procedures. -Clean the sample probe using a paper tissue moistened with a 70% alcohol solution. - Remove possible traces of salt crystals or blood at the top of the sample probe and

	probe rinse cup using a paper tissue moistened with the alcohol solution. -When necessary, gently clean the display and/or outside of the analyzer with a soft cloth, slightly moistened with water and a mild soap. Dry carefully." 2. Review of the laboratory's maintenance records from January 2017 to July 2018 revealed no Medonic maintenance records were available for review for the month of December 2017. 3. An interview with testing personnel one (as listed on Form CMS-209) on 08 /27/2018 at 15:00 hours in the office after her review of the records confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's environmental records, review of quality assurance reports, and confirmed in interview of facility personnel, the laboratory's quality assurance program failed to identify and correct that the room temperature and humidity of the laboratory was not monitored from October 27, 2017 to October 31, 2017. The findings were: 1. Review of the laboratory's environmental records from January 2017 to July 2018 revealed the room temperature and humidity of the laboratory was not documented from October 27, 2017 to October 31, 2017. 2. Review of the laboratory's quality assurance report dated November 21, 2017, stated, "The following is your Laboratory Quality Assurance Report for the month of October 2017." It further stated, "Temperatures: Laboratory Area: checked, and All readings were within acceptable ranges - Yes." 3. An interview with testing personnel one (as listed on Form CMS-209) on 08/27/2018 at 16:30 hours in the office confirmed the findings. B. Based on review of the laboratory's quality control records, review of patient results, and confirmed in interview of facility personnel, the laboratory's quality assurance program failed to identify and correct that the laboratory failed to complete performing its patient remediation when quality control was documented out of range. The findings were: 1. Review of quality control records from January 2017 to July 2018 revealed that on October 22, 2017, the laboratory stated, " ...Noticed that on 10/22/2017 two controls out of three were out. Clinic would do proper action for those patients that were run on that day." The document was approved by the laboratory director on October 18, 2017 (four days prior to when the testing was performed). 2. The laboratory was asked to provide the patient remediation records for October 22, 2017. 8 of the 28 patient records were incomplete for patient remediation (see patient alias report). 3. Interview with testing personnel one (as listed on Form CMS-209) revealed that another employee had done the remediation, but she didn't realize that he hadn't completed it. Key: CMS - Centers for Medicare and Medicaid Services
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from

	the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on random review of 5 patient charts, and interview with facility personnel, the laboratory failed to ensure patient results were available in the patient's chart. The findings were: 1. Random review of 5 patient charts revealed 1 of 5 patient charts did not contain the patient's final CBC result. 2. On August 5, 2018 Patient ID2 (DOB: 12 /18/2003, Sequence # 4539) had a CBC. 3. On 08/27/2018, the CBC result was obtained from the hematology analyzer and was checked against the patient's chart. The CBC result was not available in the chart. 4. Interview with testing personnel one (as listed on Form CMS-209) on 08/27/2018 at 16:00 hours in the laboratory confirmed the findings. She agreed the result was not available on the chart and that the patient had been charged for a CBC. Key: CMS - Centers for Medicare and Medicaid Services CBC - complete blood count ID - identification
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview of facility personnel, it was revealed that the facility failed to ensure that prior to testing patient specimens, all personnel had the appropriate education required to perform moderate complexity testing. (refer to D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview of facility personnel, it was

	revealed that the facility failed to ensure that prior to testing patient specimens, all personnel had the appropriate education required to perform moderate complexity testing. The findings were: 1. A review of personnel records revealed that one of ten personnel performing moderate complexity testing on the Medonic M Series hematology analyzer did not have documentation available, at the time of the survey, for proof of at minimum a high school diploma or equivalent. Testing person ten Date of initial testing: 12-01-2016 No longer employed date: 01-20-2017 2. An interview with testing person one (as listed on Form CMS-209) on 08/27/2018 at 14:00 hours in the office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services