Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0908313	11/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mycare Medical Of Texas, Pllc	7013 South Cage Suite C, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
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: A. 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 when performing manual reads for urinalysis testing. The findings were: 1. Surveyor observation made on November 7, 2019 at 09:50 hours in the laboratory revealed Testing Personnel #1 (as listed on Form CMS-209) reading a manual urinalysis dipstick test. She used a Siemens Multistix (lot number: 904030, expiration date: 10-31-2020). After she dipped the urine, she set the timer for 1 minute and 20 seconds and waited until the timer went off to read the results. The results were as follows: Glucose: Negative Bilirubin: Negative Ketones: Negative

	Specific Gravity: 1.020 Blood: Negative pH: 5.0 Protein: Negative Urobilinogen: 0.2 Nitrate: Negative Leukocytes: Small 2. Review of the manufacturer's instructions for the Siemens Multistix 10SG (TN30516A, Rev. 0610) stated, "If reading visually, read each pad at the time shown on the label, starting with the shortest time." 3. Review of the manufacturer's instructions for read times located on the outside labeling on the container stated: Analyte Read Time Glucose 30 seconds Bilirubin 30 seconds Ketones 40 seconds Specific Gravity 45 seconds Blood 60 seconds pH 60 seconds Protein 60 seconds Urobilinogen 60 seconds Nitrate 60 seconds Leukocytes 120 seconds 4. The findings were confirmed in interview with Testing Personnel #1 (as listed on Form CMS-209) on November 7, 2019 at 09:55 hours in the laboratory. B. 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 waived testing kits. The findings were: 1. Surveyor observation made on November 7, 2019 at 10:00 hours found no means to monitor or record the room temperature of the storage closet. The following random review of waived testing kits were stored in the storage closet: Henry Schein One Step+ Strep A Dipstick Test 1 Box OSOM Ultra Flu A & B Test 3 Boxes CardioChek Glucose Test Strips 6 Boxes Siemens MultiStix 10SG 6 Boxes 2. Review of the manufacturer's instructions for Henry Schein One Step+ Strep A Dipstick Test (Eff. Date: 2018-05-15) under "Storage and Stability" it stated, "The kit can be stored at room temperature or refrigerated (2-30 degrees Celsius ..." 3. Review of the manufacturer's instructions for OSOM Ultra Flu A & B Test (Rev. P-52631-C, 10/2018) under "Storage and Stability" it stated, "The OSOM Ultra flu A 7 B Test may be stored at 2-30 degrees Celsius (35-86 degrees Fahrenheit) in the original sealed pouch, away from direct sunlight ..." 4. Review of the manufacturer's instructions for CardioChek pts panels eGLU (PS-004580 E Rev. 2, 12/17) under "Storage and Handling" it stated, "Store test strip package in a cool, dry place at room temperature 68-86 degrees Fahrenheit (20-30 degrees Celsius) or refrigerated at 35-46 degrees Fahrenheit (2-8 degrees Celsius) before using..." 5. The findings were confirmed in interview of Testing Personnel #1 (as listed on Form CMS-209) on November 7, 2019 at 10:00 hours in the storage closet. She agreed there was no temperature monitoring device located in the closet. Key: CMS - Centers for Medicare and Medicaid Services C. Based on surveyor observation, review of manufactuer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for performing CardioChek glucose monitoring. The findings were: 1. Surveyor observation made in the laboratory on November 7, 2019 at 09:55 hours revealed Testing Personnel #1 performing a glucose check using the CardioChek analyzer. The specimen was collected in a pediatric bullet capillary tube. The blood was maintained at the tip of the capillary tube. Once she inserted the test strip into the analyzer, she tapped the capillary tube until a drop released onto the test strip. 2. Review of the manufacturer's instructions for the CardioChek eGLU test strips (PS-004580 E. Rev. 2, 12/17) under, "Directions for Use - Testing" it stated, "6. Gently touch finger to the tip of the glucose test strip to apply a 1.1 uL drop of blood. Do not press the glucose test strip into the finger." 3. Review of the final patient report revealed the glucose reading was 141 mg/dL. 4. The findings were confirmed in interview with Testing Personnel #1 (as listed on Form CMS-209) on November 7, 2019 at 09:55 hours in the laboratory. Key: CMS - Centers for Medicare and Medicaid Services mg/dL - miligrams per deciliter uL - microliter
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of

	the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policies, and confirmed in interview of facility personnel, the laboratory failed to follow its specimen labeling policy. The findings were: 1. Surveyor observation on November 7, 2019 at 09:50 hours found a pediatric purple top sample in the laboratory labeled with first and last name. 2. Review of the laboratory's policy titled, "Patient Sampling Procedure" approved by the laboratory director on January 9, 2019, stated, "C. The specimen is to be labeled with 2 unique identifiers (client name and date of birth or identification number), time and date of collection, and the initials of the person collecting the sample ..." Note: No CBC was ordered at this time. 3. The findings were confirmed in interview with Testing Personnel #1 (as listed on Form CMS-209) on November 7, 2019 at 09:52 hours in the laboratory. Key: CMS - Centers for Medicare and Medicaid Services
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 laboratory policies, review of manufacturer's instructions, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for resolution of abnormal flags on CBC tests (Complete Blood Count). The findings were: 1. Based on review of the laboratory's policy titled, "Medonic M Series Actions Protocol for WBC Diffferential Flags" approved by the laboratory director on January 9, 2019 stated, " ...If flags persist then redraw the patient using an EDTA tube that may be transported for testing at a Reference Laboratory." 2. A review of the CDS M Series hematology analyzer operator's manual (PN 203129A, R12.13.10) revealed: "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." 3. A random review of finalized patient results from September 1, 2019 to October 31, 2019 revealed the following patient results with flags in the differential portion of the results. However, the laboratory failed to provide documentation of following its procedure to verify results by sending them out for analysis prior to releasing the result: Date SEQ# Flag (s) 09-25-2919 4226 OM 09-27-2019 4331 OM 10-01-2019 4529 OM 10-31-2019 4996 OM Note on File: "Provider said it was ok. We ran 2 more and came the same." 4. The laboratory was asked to provide documentation of sending the specimens out as required by its policy. No

	documentation was provided. 5. An interview with Testing Personnel #1 (as listed on Form CMS-209) on November 7, 2019 at 11:00 hours in the laboratory confirmed the findings. Key CMS - Centers for Medicare and Medicaid Services
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 laboratory policies, manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor the room temperature where laboratory items were stored. The findings were: 1. Surveyor observation made on November 7, 2019 at 10:00 hours found no means to monitor or record the room temperature of the storage closet. The following random review of laboratory items were stored in the storage closet: BD yellow top tubes Lot: 9123768 Expiration Date: 04-30-2020 Quantity: 100 tubes BD yellow top tubes Lot: 9165861 Expiration Date: 06-30-2020 Quantity: 100 tubes BD purple top tubes Lot: 9065805 Expiration Date: 07-31-2020 Quantity: 100 tubes BD purple top tubes Lot: 9184931 Expiration Date: 11030-2020 Quantity: 100 tubes BD gray top tubes Lot: 8215742 Expiration Date: 01-30-2020 Quantity: 100 tubes BD Blue top tubes Lot: 903654 Expiration Date: 11-30-2019 Quantity: 100 tubes Fisher Finest Bacteriology Culture Collection and Transport System Lot: 8e10A Expiration Date: 05-10-2020 Quantity: 100 swabs 2. Review of the laboratory's policy titled, "Storage and Temperature of Reagents and Supplies" approved by the laboratory director on January 9, 2019, it stated, "All reagents and supplies must be stored at the appropriate temperatures. For refrigerated temperatures - the temperature requirement is 36- 46 degrees Fahrenheit or 2.2 - 7.7 degrees Centigrade. For ambient temperature it is 18 - 25 degrees Centigrade." 3. Review of manufacturer's instructions for BD collection tubes, located on the outside of the package labeling stated, "Store tubes at 4-25 degrees Celsius." 4. Review of manufacturer's instructions for Fisher swabs, located on the outside of the package labeling stated, "Store between 4-25 degrees Celsius or 40-77 degrees Fahrenheit." 5. The findings were confirmed in interview of Testing Personnel #1 (as listed on Form CMS-209) on November 7, 2019 at 10:00 hours in the storage closet. She agreed there was no temperature monitoring device located in the closet. Key: CMS - Centers for Medicare and Medicaid Services BD - Becton Dickinson
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final patient results and confirmed in interview of facility personnel, the laboratory failed to ensure the name and address of the testing facility was available on patient reports. The findings were: 1. Review of 30 random patient CBC results from September 1, 2019 to November 5, 2019 revealed the following six final patient results did not include the name and address of the facility: Date of Service: November 5, 2019 Patient Initials Sequence # DS 5054 AH 5055 SE 5057 BM 5058 AN 5056 LB 5021 2. The findings were confirmed in interview with Testing Personnel #1 (as listed on Form CMS-209) on November 7, 2019 at 11:30 hours in the laboratory. She confirmed the printer was having problems that day, but it was fixed on the 6th. Key: CMS - Centers for Medicare and Medicaid Services