Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0982501	05/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mycare Medical Of Texas Pllc	2121 E Griffin Parkway Suite 10, Mission, 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(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 review of the manufacturer's instructions for the Cell Dyn Emerald hematology controls, a random review of quality control records from October 2022, November 2022 and February 2023, review of patient test records from October 2022, November 2022, and February 2023, and staff interview, it was revealed the laboratory used quality control material past it's revised expiration date. The findings include: 1. A review of the manufacturer's instructions for the Cell Dyn Emerald hematology control (9231582B 3500006-5 August 2018) revealed the manufacturer stated the stability of the control material was 8 consecutive days once opened. 2. A sampling of quality control records from October 2022, November 2022 and February 2023 identified the following times when the laboratory documented control material was used for more than 8 days after opening. a) Control Lot: 2206 Opened: 10/7/2022 Last use date: 10/15/2022 Days used: 9 days b) Control Lot: 2290 Opened: 11/10 /2022 Last use date: 11/18/2022 Days used: 9 days c) Control Lot: 3009 Opened: 2/3 /2023 Last use date: 2/13/2023 Days used: 11 days 3. A review of patients test records from October 2022, November 2022, and February 2023 identified the following patients whose samples were tested on days which expired control material was tested: a) 10/15/2022 Patient ID: 19750 Patient ID: 22932 Patient ID: 43536 Patient ID: 25332 Patient ID: 34345 Patient ID: 46969 Patient ID: 14756 Patient ID: 35080

	Patient ID: 39822 Patient ID: 47064 Patient ID: 49868 Patient ID: 18877 Patient ID: 21430 Patient ID: 41538 Patient ID: 18524 b) 11/18/2022 Patient ID: 32735 Patient ID: 46203 Patient ID: 48467 Patient ID: 31460 Patient ID: 50262 Patient ID: 19690 Patient ID: 49037 Patient ID: 31459 Patient ID: 34070 Patient ID: 47098 Patient ID: 50254 Patient ID: 42231 Patient ID: 39123 Patient ID: 37963 Patient ID: 41945 Patient ID: 47038 Patient ID: 37410 Patient ID: 17958 Patient ID: 43844 Patient ID: 40103 Patient ID: 46204 Patient ID: 35705 Patient ID: 49434 Patient ID: 33691 Patient ID: 39375 Patient ID: 20125 Patient ID: 45257 Patient ID: 40938 Patient ID: 45258 Patient ID: 19562 Patient ID: 49433 c) 2/11/2023 Patient ID: 48711 Patient ID: 40078 Patient ID: 45283 Patient ID: 42226 Patient ID: 38548 Patient ID: 16176 Patient ID: 31947 Patient ID: 18771 Patient ID: 38380 Patient ID: 31237 Patient ID: 15869 Patient ID: 36295 Patient ID: 35867 Patient ID: 40293 Patient ID: 37670 Patient ID: 42687 Patient ID: 45914 Patient ID: 27561 d) 2/13/2020 Patient ID: 26930 Patient ID: 26682 Patient ID: 40657 Patient ID: 17336 Patient ID: 16352 Patient ID: 50975 Patient ID: 41299 Patient ID: 47215 Patient ID: 50335 Patient ID: 28820 Patient ID: 48391 Patient ID: 37183 Patient ID: 46189 Patient ID: 40174 Patient ID: 24335 Patient ID: 48762 Patient ID: 46228 Patient ID: 18292 Patient ID: 31513 Patient ID: 35444 Patient ID: 31923 Patient ID: 48646 Patient ID: 42313 Patient ID: 47075 Patient ID: 49860 Patient ID: 49871 Patient ID: 42401 Patient ID: 37020 Patient ID: 15051 Patient ID: 49957 Patient ID: 46133 4. An interview with the technical consultant on 05/02/203 at 1200 hours in the biller's room - after her review of the records- confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies performed on the Cell Dyn Emerald hematology analyzer in January 2022, and staff interview, it was revealed the laboratory failed to have documentation of evaluating the results of accuracy and linearity studies. The findings include: 1. A review of the laboratory's verification studies performed on the Cell Dyn Emerald hematology analyzer in January 2022 revealed the laboratory failed to have documentation of the evaluation of accuracy and linearity studies to determine if the studies met the laboratory criteria for acceptability. 2. The laboratory was asked to provide documentation of evaluating the accuracy and linearity studies. No documentation was provided. 3. The laboratory reported performing 53,886 hematology tests annually. 4. An interview with the technical consultant on 05/02/2023 at 0910 hours in the biller's room - after her review of the records - confirmed the findings.
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 the manufacturer's instructions for the Cell Dyn Emerald hematology analyzer, review of the laboratory's maintenance records from January 2022 to December 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing the six month maintenance of lubricating the pistons in 2022. The findings include: 1. A review of the manufacturer's instructions for the Cell Dyn Emerald revealed the manufacturer required the lubrication of the pistons to be performed every six months. 2. A review of the laboratory's Cell Dyn Emerald maintenance records from January 2022 to December 2022 revealed the laboratory failed to have documentation of performing the required maintenance in 2022. 3. The laboratory was asked to provide documentation of performing the required maintenance. No documentation was provided. 4. An interview with the technical consultant on 05/02/2023 at 1115 hours in the laboratory - after her review of the records- confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration verification records from November 2021 to November 2022 revealed the laboratory failed to have documentation of performing 2 of 8 calibration verifications in 2021 on the Roche Elecsys 2010 system and 2 of 44 calibration verifications in 2022 on the Roche Cobas Integra 400 Plus analyzer. The findings include: 1. A review of the laboratory's calibration verifications performed on the Roche Elecsys 2010 system in November 2021 revealed the laboratory failed to have documentation of performing calibration verifications for PSA and Free T4. 2. A review of the laboratory's calibration verification performed on the Roche Cobas Integra 400 Plus analyzer in October 2022 revealed the laboratory

	failed to have documentation of performing calibration verification for CK and A1C. 3. The laboratory was asked to provide documentation of performing the required calibration verifications. No documentation was provided. 4. An interview with the technical consultant on 05/02/2023 at 1209 hours in the biller's room - after her review of the records - confirmed the findings.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's verification studies for the Cell Dyn Emerald hematology analyzer, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments for 3 of 3 testing personnel after a new methodology introduced. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 testing personnel. 2. A review of the laboratory's verification studies for the Cell Dyn Emerald hematology analyzer revealed the analyzer was placed into use in January 2022. 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing competency assessments prior to personnel performing patient testing. 4. The laboratory was asked to provide documentation of the required competency assessments being performed. No documentation was provided. 5. An interview with the technical consultant on 05/02/2023 at 0945 hours in the biller's room 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 submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the training for 3 of 3 testing personnel for the Cell Dyn Emerald hematology analyzer. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 testing personnel. 2. A review of the laboratory's verification studies for the Cell Dyn Emerald hematology analyzer revealed the analyzer was placed into use in January 2022. 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for 3 of 3 testing personnel on the Cell Dyn Emerald hematology analyzer. 4. The laboratory was asked to provide documentation of training. No documentation was provided. 5. An interview with the technical consultant on 05/02/2023 at 0945 hours in the biller's room confirmed the findings.