

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2089661	(X3) Date Survey Completed 02/03/2023
Name of Provider or Supplier Plaza Del Carmen Medical Services Inc	Street Address, City, State Carr 891, Km 1 Hm 7 Bo Pueblo, Corozal, PR	
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
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2022) and assistant administrator interview on February 3, 2023 at 9:37 a.m., it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results in platelets test in the second testing event performed in June 2022. The findings include: 1. Puerto Rico Proficiency Testing Program records were reviewed from February 2022 to December 2022. (review on 2/3/2023 at 9:37 a.m.) 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in platelets test in the second testing event performed in June 2022. No remedial actions were taken. (review on 2/3/2023 at 9:40 a.m.) 3. The assistant administrator confirmed on February 3, 2023 at 9:45 a.m. , that the laboratory failed to take remedial actions when obtained unsatisfactory results of 60 percent in platelet test in June 2022.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on laboratory testing personnel records review (2022) and administrative personnel interview on February 3, 2023 at 11:30 AM, it was determined that the laboratory technical supervisor (director) failed to follow the established schedule for testing personnel and clinical consultant competence evaluation. The findings include: 1. The laboratory schedule for testing personnel and clinical consultant competence evaluation showed that it must be performed every year. (review on February 3, 2023 at 11:35 a.m.) 2. The technical supervisor did not perform the testing personnel (MT # 1) and clinical consultant competence evaluation since August 2021. (review on February 3, 2023 at 11:35 a.m.) 3. The administrative personnel confirmed on February 3, 2023 at 11:35 a.m. , that the competence evaluation were not performed as established.

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:

1. Based on observation at the laboratory bleeding area, patient results review, hematology quality controls review, reference laboratory worksheets and interview with the administrative personnel on February 3, 2023 at 9:00 a.m., it was determined that the laboratory used sample collection tubes with exceeded expiration date when processed and reported 215 Complete Blood Count (CBC) and referred 61 CBC and 86 glycohemoglobin tests to reference laboratory. The findings include: a. On February 3, 2023 at 9:00 a.m. the laboratory bleeding area (sample collection) was reviewed. b. During the inspection performed to the laboratory bleeding area at 9:10 a. m. the surveyor found twenty (20) ethylenediaminetetraacetic acid (EDTA) violet tubes, lot number 1160779, exp. date 10/31/2022. c. Review of patient records showed that 215 CBC patients samples were collected and processed in the laboratory with the expired tubes from November 1, 2022 to February 2, 2023. (review on 2/3 /2023 at 10:15 a.m.) d. During the survey on February 3, 2023 at 11:20 a.m., the copy of the patients CBC test results were reviewed, showing mostly of them were within the normal values. From November 2022 to January 2023 six patient samples with panic values were found. Three out of six patients were patient with historical values of low hemoglobin and hematocrit results. Also quality controls graphs were reviewed no deviations were detected those months. e. Review of patient records showed that sixty one (61) CBC and eighty six (86) glycohemoglobin test (Hgb A1c) patients samples were collected and referred to the reference laboratory with the expired samples tubes from November 1, 2022 to January 31, 2023. (review on 2/3/2023 at 10:15 a.m.) f. The administrative personnel (IO) confirmed on February 3, 2023 at 10:30 a.m. that those EDTA tubes were expired. 2. Based on observation at the laboratory bleeding area, reference laboratory worksheets and interview with the administrative personnel on February 3, 2023 at 9:12 a.m., it was determined that the laboratory collected PT (prothrombin time) and PTT- (partial thromboplastin time) patient samples with expired collection tubes. The findings include: a. On February 3, 2023 at 9:10 a.m. the laboratory bleeding area (sample collection) were reviewed. b.

During the inspection performed to the laboratory bleeding area at 9:10 a.m. the surveyor observed that eleven (11) Buffered Sodium Citrate 3.2 % pale blue top tubes, lot number A211235 with expiration date 12/1/2022. c. Review of reference laboratory log sheets showed that three PT /PTT patients samples were collected and referred on 1/18/23 and 1/24/23 with the expired tubes. (review on 2/3/2023 at 10:15 a.m.) d. The administrative personnel (IO) confirmed on February 3, 2023 at 10:30 a. m. that those blue top tubes were expired. 3. Based on observation at the laboratory bleeding area, reference laboratory worksheets and interview with the administrative personnel on February 3, 2023 at 9:16 a.m., it was determined that the laboratory collected two (2) ear culture with expired transport swabs. The findings include: a. On February 3, 2023 at 9:10 a.m. the laboratory bleeding area (sample collection) was reviewed. b. During the inspection performed to the laboratory bleeding area at 9:16 a. m. the surveyor observed eleven (11) sterile transport swab, lot number 2101876 with expiration date 12/31/2022. c. Review of reference laboratory log books showed that two ear culture samples were collected and referred on 1/4/2023 and 1/31/2023 with those expired swab. (review on 2/3/2023 at 10:15 a.m.) d. The administrative personnel (IO) confirmed on February 3, 2023 at 10:30a.m. that those transport swab were expired. 4. Based on observation at the laboratory hematology area, patient test results review and interview with the administrative personnel on February 3, 2023 at 11:45 a.m., it was determined that the laboratory used the Wright stain reagents kit with exceeded expiration date when performed and reported 13 manual differential from 7/12/2022 to 9/29/2022. The findings include: a. On February 2, 2023 at 11:50 a. m., the surveyor observed inside a counter in the hematology area a bottle of Wright stain reagent with exceeded expiration date: Lot: 1098-01, exp. date : 6/30/2022. b. Hematology patients test results were reviewed from 7/12/2022 to 9/29/2022 . The records showed that the laboratory used this expired reagent the following days: 07/12 /22, 8/2/2022, 8/3/2022, 8/4/2022, 8/15/2022, 8/16/2022, 9/2/2022, 9/9/2022, 9/20 /2022 and 9/29/2022. (review on 2/3/2023 at 11:55 a.m.) c. The administrative personnel confirmed on February 3, 2023 at 11:55 a.m., that the laboratory used this stain reagents with exceeded expiration date. 5. Based on observation at the laboratory area, endocrinology patient test worksheets review and interview with the administrative personnel on February 3, 2023 at 11:00 a.m., it was determined that the laboratory used a human chorionic hormone (hCG- pregnancy test - Alere) test with exceeded expiration date when performed and reported two hCG tests on 12/20/22 and 1/26/23. The findings include: a. On February 2, 2023 at 11:05 a.m., the surveyor observed a hCG box over the counter ;lot: HCG-0122090 with exceeded expiration date: 11/30/22. The box contained 19 expired cartridge. b. Endocrinology patient test worksheets were reviewed from January 2022 to February 2, 2023 . The records showed that the laboratory used this expired reagent the following days: 12/20/2022 (patient id- 2199 and 1/26/2033 (patient id - 0173) (review on 2/3/2023 at 11:10 a.m.) c. The administrative personnel confirmed on February 3, 2023 at 11:55 a.m., that the laboratory used this hCG kit with exceeded expiration date.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on observation of laboratory bleeding area , laboratory testing area, Puerto Rico

	<p>Proficiency Program testing records review (2022) and administrative personnel interview on February 3, 2023 at 12:20 p.m., it was determined that the laboratory director did not ensure that proficiency testing samples were tested as required under Subpart H requirements and did not ensure that the general supervisor (testing personnel) used expired collection materials (tubes and transport swab) to collect patient samples. Refer to D2128 and D5417.</p>
<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing records review (2022) and administrative personnel interview on February 3, 2023 at 12:20 P.M., it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2128.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on observation of laboratory bleeding area , laboratory testing area and administrative personnel interview on February 3, 2023 at 12:20p.m., it was determined that the laboratory director did not ensure that the laboratory supplies and reagents (EDTA tubes, Sodium citrate, transport swab, wright stain, hCG cartridge kit) must not be used when they have exceeded their expiration date. Refer to D5417.</p>
<p>D6144</p>	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>This STANDARD is not met as evidenced by: Based on observation of laboratory bleeding area , laboratory testing area and administrative personnel interview on February 3, 2023 at 12:20 p.m., it was determined that the laboratory general supervisor (testing personnel) used expired collection materials (tubes and transport swab) to collect patient samples. Refer to D5417.</p>