| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D2089661 | 07/23/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Plaza Del Carmen Medical Services Inc | 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 |
|---|---|
| **D5012** | SYPHILIS SEROLOGY<br>CFR(s): 493.1207<br><br>If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on syphilis serology testing record review ( year 2018-2019) and laboratory director interview on July 23, 2019 at 11:20 A.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology tests. The finding includes: 1. The laboratory failed to follow the manufacturer's instruction when patients specimens were tested for syphilis serology tests by the rapid plasma reagin (RPR) method. Refer to D5405. |
| **D5201** | CONFIDENTIALITY OF PATIENT INFORMATION<br>CFR(s): 493.1231<br><br>The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of quality assessment records ( year 2018 ) and laboratory director interview on July 23, 2019 at 10:00 A.M, it was determined that the laboratory failed to have written procedures to ensure confidentiality of patient information throughout all phases of the testing process that are under the laboratory control. The findings include: 1. The laboratory did not perform in 2018 an evaluation to ensure confidentiality of patient information throughout all phases of the testing process that are under the laboratory control. 2. The new laboratory director confirmed on July 23, |

| | |
|---|---|
| | 2019 at 9:30 A.M., that in 2018 the laboratory did not have written procedures to ensure confidentiality of patient information and failed to perform an evaluation to ensure confidentiality of patient information. 3. This deficiency was cited on the last survey performed on December 13, 2017. |
| **D5205** | COMPLAINT INVESTIGATIONS<br>CFR(s): 493.1233<br><br>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment (QA) written procedures review , lack of QA records ( 2018) and laboratory director interview on July 23, 2019 at 9:45 AM, it was determined that the laboratory failed to have written procedures to document and evaluate any complaint submitted and problems reported. The findings include: 1. Quality Assessment (QA) written procedures were reviewed from 2018-2019. 2. In 2018 the laboratory did not document or evaluate any complaint submitted to the laboratory. 3. The new laboratory director confirmed on July 23, 2019 at 9:45 A.M., that the laboratory did not document or evaluate any complaint submitted to the laboratory in 2018. 4. This deficiency was cited on the last survey performed on December 13, 2017. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack quality assessment procedure manual in 2018, quality assessment records review (2018) and laboratory director interview on July 23, 2019 at 11:40 AM, it was determined that the laboratory failed to established Quality Assessment Program to monitor and evaluate the following requirements for general laboratory systems: confidentiality of patient information and complaint The findings include: 1. The laboratory failed to have written procedures to ensure confidentiality of patient information . Refer to D5201. 2. The laboratory failed to have written protocol in order to evaluate and document any complaint. Refer to D5205. 3. The laboratory director confirmed on July 23, 2019 at 11: 40 A.M, that evaluations to confidentiality of patient information and complaint were not performed in 2018. |
| **D5391** | PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1249(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on lack Quality Assessment (QA) records (2018) and laboratory director interview on July 23, 2019 at 10:00 AM, it was determined that the laboratory failed to have Quality Assessment Program to monitor and evaluate the requirement for pre-analytic systems. The findings include: 1. Quality Assessment (QA) written procedures were reviewed from 2018-2019. 2. The laboratory did not evaluate the following QA assessment for pre- analytic systems. in 2018: a. Test requests b. Specimen submission, c. Specimen handling. d. Specimen referral. 3. The new laboratory director confirmed on July 23, 2019 at 10:00 A.M., that the pre analytic system was not evaluated in 2018. 4. This deficiency was cited on the last survey performed on December 13, 2017. |
| **D5405** | PROCEDURE MANUAL<br>CFR(s): 493.1251(c)<br><br>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on syphilis serology quality control records review ( year 2018-2019) and laboratory director interview on July 23, 2019 at 11:20 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when patients specimens were tested for syphilis serology tests by the rapid plasma reagin (RPR) method. The findings include: 1. The ASI manufacturer's instruction establishes that three levels of control material ( non reactive, minimal to moderate and reactive) must be included each day of testing. 2. Syphilis serology quality control records were reviewed since January 2018. 3. The laboratory did not include the three levels of control materials during the following days: 7/13/19 ( patient specimen # 1952) and 7/27/19 (patients specimens # 1600, 1601). 4. The new laboratory director confirmed on July 23, 2019 at 11:20 AM, that the laboratory failed to follow the manufacturer's instruction when patients specimens were tested for syphilis serology tests by the rapid plasma reagin (RPR) method. |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by: |

| | |
|---|---|
| | Based on hematology calibration records reviewed ( year 2018-2019) and laboratory director interview on July 23, 2019 at 10:40 a.m., it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (annually) for the hematology tests performed by the Sysmex system. The findings include: 1. The laboratory uses a Sysmex hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that the laboratory perform the calibration verification procedures annually. 3. The records showed that the laboratory did not perform at least annually the calibration verification procedures for the Sysmex hematology system. 4. The last calibration verification procedures was performed on May 23, 2018. 5. The new laboratory director confirmed on July 23, 2019 at 10:40A. M., that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (annually) . 6. This deficiency was cited on the last survey performed on December 13, 2017. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on routine chemistry quality control records review ( year 2018-2019) and laboratory director interview on July 23, 2019 at 10:50 A.M., it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry (electrolytes) tests processed by the Vitros system. The findings include: 1. The laboratory uses a Vitros system for routine chemistry tests. 2. From January 2018 to July 2019, the records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry (electrolytes) tests processed by Vitros system. 3. The last calibration verification procedures for the routine chemistry ( electrolytes) tests processed by Vitros system was performed in November 2018. 4. The new laboratory director confirmed on July 23, 2019 at 10:50 A.M. , that the laboratory did |

| | |
|---|---|
| | not perform at least 6 months the calibration verification procedures for electrolytes performed by the Vitros system since November 2018. 5. This deficiency was cited on the last survey performed on December 13, 2017. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of routine chemistry statistical parameters since April 2019 and interview with the laboratory director on July 23, 2019 at 11:15 A.M., it was found that the laboratory it was found that the laboratory did not evaluate nor define the statistical values of the commercial control material used by the Vitros system. The findings include: 1. The laboratory performed routine chemistry test by Vitros 250 system. 2. Quality control evaluation were reviewed from January 2018 to April 2019. 3. The laboratory did not have any statistical data (Levy-Jennings, control value mean and limits) of the control materials used since April 2019. 4. The new laboratory director confirmed on July 23, 2019 at 11: 20 A.M., that the laboratory did not evaluate nor define the statistical values of control material used by the Vitros 250 system since April 2019. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack Quality Assessment (QA) records ( year 2018) and laboratory director interview on July 23, 2019 at 11:30 AM, it was determined that the laboratory failed to have written procedures to monitor and evaluate the requirement for post- analytic systems. The findings include: 1. The laboratory did not evaluate the following QA assessment for post- analytic systems. in year 2018: a. Turn around time b. Test report 2. The new laboratory director confirmed on July 23, 209 at 11:30 AM , that the QA program was not evaluated in 2018. 3. This deficiency was cited on the last survey performed on December 13, 2017. |
| **D6076** | LABORATORY DIRECTOR |

| | |
|---|---|
| | CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on quality control records review ( year 2018-2019) , lack of quality assessment records( 2018) and laboratory director interview on July 23, 2019 at 11:30 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the general laboratory system , pre- analytic, analytic and post- analytic systems. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems and quality assessment requirements. Refer to D 6093 and D 6094. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on syphilis serology, hematology, routine chemistry quality control records review ( 2018-2019) and interview with the laboratory director on July 23, 2019 at 11: 35 A.M.. it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems: syphilis serology, routine chemistry and hematology tests. Refer to D5405, D5437, D5439 and D5469. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Assessment (QA) records ( year 2018) and laboratory director interview on July 23, 2019 at 11:45 A.M, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records showed that in 2018 the laboratory did not evaluate nor establish a Quality Assessment Program to monitor and evaluate the requirements for general laboratory system, preanalytic, analytic and postanalytic systems. 2. The laboratory director confirmed on July 23, 2019 at 11: 45 A..M, that the QA requirements were not evaluated in 2018. Refer to D5291, D5391 and D5891. |
| **D6141** | GENERAL SUPERVISOR<br>CFR(s): 493.1459 |

| | |
|---|---|
| | The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on laboratory director interview on July 23, 2019 at 11:30 A.M., it was determined that the laboratory general supervisor position was not fill since June 30, 2019. The finding includes: 1. The laboratory director stated on July 23, 2019 at 11:30 A.M., that the laboratory general supervisor position was not fill since June 30, 2019. 2.This deficiency was cited on the last survey performed on December 13, 2017. |
| **D6177** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1495(b)(3)<br><br>Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control records review ( year 2018-2019) and laboratory director interview on July 23, 2019 at 11:30 AM, it was determined that testing personnel failed to follow quality control procedures. The findings include: 1. The laboratory testing personnel failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (annually) for the hematology tests performed by the Sysmex system. Refer to D5437. 2. The laboratory testing personnel failed to perform at least every 6 months the calibration verification procedures for the routine chemistry (electrolytes) tests processed by the Vitros system. Refer to D5439. 3. The laboratory failed to follow the manufacturer's instruction when patients specimens were tested for syphilis serology tests by the rapid plasma reagin (RPR) method. Refer to D5405. 4. The laboratory did not evaluate nor define the statistical values of the commercial control material used by the Vitros system. Refer to D5469. |