| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0503810 | 01/04/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Mission Pediatric Center | 210 South Bryan Road Suite 5a, 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 |
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| **D0000** | The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems 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. |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's American Proficiency Institute's proficiency testing records, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director and testing personnel signing 1 of 3 attestation statements. The findings include: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2021 (events 1, 2 and 3) revealed the laboratory failed to have documentation of the laboratory director and testing personnel signing 1 of 3 attestation statements. The missing attestation statement was from: 2021 Event 1 2. The laboratory was asked to provide documentation of the signed attestation statement. No documentation was provided. 3. |

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| | An interview with the technical consultant on 01/04/2022 at 1030 hours in the break room - after her review of the records- confirmed the findings. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory's records and staff interview, it was determined the laboratory failed to meet the requirements for analytic systems. The findings include: 1. The laboratory failed to follow its policy for flagged CBC results (refer to D5403). This is a repeat deficiency from the surveys conducted 1/26/2016, 12/7/2017 and 11/11 /2020 2. The laboratory failed to have documentation of verifying new lots of control material (refer to D5469). This is a repeat deficiency from the survey conducted 11/11 /2020 |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies, review of patient test records, and staff interview, it was revealed the laboratory failed to follow its policy for flagged complete blood count (CBC) results. The findings include: 1. A review of the laboratory's policy titled "Policy for Abnormal Differentials" (approved by the laboratory director 01/02/2021) revealed: "Report will not display flagged results." 2. A sampling of patient test records from October 2021 to December 2021 identified the following CBC results which were reported to the provider with flagged results. a) |

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| | October 2021 Date: 10/02 ID: 000006185 Flag: * Lymph % Mono % Gran % Lymph # Mono # Gran # Date: 10/27 ID: 000006291 Flag: * RDW Date: 10/27 ID: 000006293 Flag: * RDW Date: 10/30 ID: 000006311 Flag: M Mono % Gran % Lymph # Mono # Gran # b) November 2021 Date: 11/01 ID: 000006327 Flag: * RDW Date: 11/03 ID: 000006346 Flag: * Gran # Date: 11/11 ID: 0000006409 Flag: 2 Lymph % Date: 11/15 ID: 000006417 Flag: 2 Lymph % Date: 11/17 ID: 0000006432 Flag: 2 Lymph % Date: 11/18 ID: 000006444 Flag: * Mono % Platelet MPV Date: 11 /19 ID: 000006448 Flag: 3 Gran % Date: 11/22 ID: 000006452 Flag: * Platelet MPV Date: 11/24 ID: 000006467 Flag: * Platelet MPV Date: 11/24 ID: 000006463 Flag: * Mono % Date: 11/26 ID: 000006476 Flag: * Gran % Date: 11/29 ID: 000006485 Flag: * Platelet MPV c) December 2021 Date: 12/01 ID: 000006501 Flag: 2 Mono % Date: 12/10 ID: 000006548 Flag: * RDW Date: 12/14 ID: 000006562 Flag: * WBC Date: 12/20 ID: 000006592 Flag: * RDW 3. An interview with the technical consultant on 01/04/2022 at 1040 hours in the break room - after her review of the records- confirmed the findings. Key: Lymph - lymphocytes Mono- monocytes Gran - granulocytes % - percent # - number RDW - red cell width MPV- mean platelet volume WBC- white blood cell NOTE: This is a repeat deficiency from the surveys conducted 1/26/2016, 12/7/2017 and 11/11/2020 |
| **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 review of the laboratory's polices, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to have documentation of verifying 5 of 5 new lots of control material. The findings include: 1. A review of the laboratory's policy titled "Quantitative Control Policy" (approved by the laboratory director on 12/24/2013) revealed: "Controls will be run concurrently with patients for at least 3 days." 2. A review of the laboratory's quality control records from 2021 revealed the laboratory placed the following lots of Coulter 4C-ES control material into use without documentation of following its policy to verify the new lots: Lot: 8600 expiration: 01/04/2021 Lot: 9700 expiration: 06/07/2021 Lot: 7800 expiration: 08/30/2021 Lot: 8600 expiration: 12/25/2021 Lot: 9100 expiration: 02/28/2022 3. An interview with the technical consultant on 01/04/2022 at 1100 hours in the break room - after her review of the records- confirmed the findings. NOTE: This is a repeat deficiency from the survey conducted 11/11/2020 |
| **D6019** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iv) |

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| | The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2020 and 2021, and staff interview, it was revealed the laboratory director failed to ensure corrective action were performed for failed proficiency testing results. The findings include: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2020 and 2021 revealed the laboratory failed to attain acceptable results for 2020 Hematology/Coagulation event 3. The failed scores were: Erythrocyte count 40% MCHC 60% MCV 40% MPV 40% Platelet count 40% RDW 40% 2. The laboratory was asked to provide documentation of performing corrective actions. No documentation was provided. 3. An interview with the technical consultant on 01/04/2022 at 0930 hours in the break room revealed she had instruction the laboratory to rerun the samples or perform a split sample analysis, however she could not find documentation of this being performed. This confirmed the findings. Key MCHC - mean corpuscular hemoglobin volume MCV - mean corpuscular volume MPV- mean platelet volume RDW - red cell width |
| **D6045** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(7)<br><br>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, manufacturer's instructions, patient reports, and confirmed in interview, the technical consultant failed to identify training needs of testing personnel. The findings include: Testing personnel were not: 1. Following the laboratory's policies (refer to D5403). 2. Following the laboratory's quality policies (refer to D5469). |