Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0872915	(X3) Date Survey Completed 01/04/2023
Name of Provider or Supplier Medical Center Pediatrics	**Street Address, City, State** 5793 W Maple Road Suite 153, West Bloomfield, MI	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with Testing Personnel (TP) #1, the laboratory failed to retain the Beckman Coulter DxH520 hematology analyzer quality control, patient printouts, and background counts for 2 (2021 and 2022) of 2 years reviewed. Findings include: 1. A record review revealed for 2 (2021 and 2022) of 2 years the Beckman Coulter analyzer quality control records were not retained as follows: Quality Control records a. 1/04/2021 b. 4/01/2021 Background counts a. 1/04/2021 b. 4/01/2021 c. 8/17/2021 d. 10/07/2021 e. 2/04/2022 f. 5/10/2022 g. 9/20/2022 2. A record review revealed for 2 (2021 and 2022) of 2 years that once the monthly quality control documents were printed the daily background counts were discarded and not retained for 2 years. 3. A record review revealed a lack of documentation of hematology quality control records and patient printouts from 1/04/2021 to 8/17/2021 were not available on the day of the survey. 4. An interview on 1/04/2023 at 1:08 pm, TP#1 confirmed the above listed Beckman Coulter DxH520 quality control records, patient printouts, and background counts were not available on the day of the survey.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to perform and document the refrigerator temperatures and perform and document thermometer calibrations. Refer to D5431 A & B. 2. The laboratory failed to perform quality control testing at least each day of patient testing for its hematology complete blood count. Refer to D5445. 3. The laboratory failed to document corrective action for improper temperature of the Lab-Line Instruments Inc. incubator used for the Group A beta hemolytic streptococcus bacteriology testing. Refer to 5785. 4. The laboratory failed to monitor and evaluate the analytic system assessment activities for problems and make corrections to prevent recurrence of the problems. Refer to D5793.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: A. Based on observation, lack of documentation, and interview with the Testing Personnel (TP) #1, the laboratory failed to perform and document the refrigerator temperatures for 2 (2021 and 2022) of 2 years reviewed. Findings include: 1. During a tour of the laboratory on 1/04/2023 at 9:20 am, the surveyor observed the Sanyo refrigerator that housed the hematology controls, the bacteriology Strep A media plates, and the Bacitracin discs had a thermometer for temperature taking. 2. A review of laboratory records showed a lack of documentation of the refrigerator temperatures for 2 of 2 years. 3. When queried on 1/04/2023 at 9:20 am, TP#1 stated that they did not record the temperatures of the refrigerator. 4. A interview on 1/04/2023 at 9:20 am, the TP#1 confirmed the laboratory did not perform and document refrigerator temperatures on each day of laboratory testing. B. . Based on observation, lack of documentation, and interview with the Testing Personnel (TP) #1, the laboratory failed to perform and document the traceable thermometer calibration checks as required by the manufacturer before the expiration for 1 (Fisher Scientific thermometer) of 1 thermometers in use for performing and documenting the room temperature and humidity. Findings include: 1. During a tour of the laboratory on 1/04 /2023 at 9:20 am, the surveyor observed the Fisher Scientific thermometer in use for the monitoring of the room temperature and humidity in use past the expiration date of 8/11/2012. 2. A lack of documentation upon review of the laboratory records revealed the thermometer was not calibrated and/or replaced by the expiration of 8/11 /2012. 3. A interview on 1/04/2023 at 9:26 am, the TP #1 confirmed the thermometer was not calibrated and/or replaced.
D5445	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(1)(2)(g) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with Testing Personnel (TP) #1, the laboratory failed to perform quality control testing at least each day of patient testing for its hematology complete blood count testing for 2 days (1/04/2021 and 4/01/2021) of 2 years of records reviewed. Findings include: 1. A review of the laboratory's quality control documentation for the Beckman Coulter DxH520 hematology analyzer revealed a lack of documentation for 2 days (1/04/2021 and 4/01/2021) of 2 years of records reviewed. 2. An interview on 1/04/2023 at 11:44 am, TP #1 confirmed the laboratory was not able to provide the surveyor the documentation requested for the 2 days of testing listed above.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to document corrective action for improper temperature of the Lab-Line Instruments Inc. incubator used for the Group A beta hemolytic streptococcus bacteriology testing for 21(January 2021 - December 2022) of 24 months of operation. Findings include: 1. A record review of the "Log For General Lab Maintenance" form revealed for 21 of 24 months reviewed, the incubator temperature was above the stated range of 35-37 degrees centigrade and no corrective action was documented as follows: 2021 a. January - 20 days b. February - 19 days c. March - 19 days d. April - 12 days e. June - 5 days f. August - 20 days g. September - 13 days h. October - 7 days i. November - 4 days j. December - 9 days 2022 a. January - 4 days b. February - 17 days c. March - 15 days d. April - 21 days e. May - 21 days f. June - 22 days g. July - 19 days h. August - 23 days i. October - 10 days j. November - 20 days k. December - 5 days 2. A interview on 1/04/2023 at 12:45 pm, TP#1 confirmed that no corrective action was documented for the incubator temperatures out of the stated range.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures

	necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with Testing Personnel (TP) #1, the laboratory failed to monitor and evaluate the analytic system assessment activities for problems and make corrections to prevent recurrence of the problems for 2 (2021 and 2022) of 2 years reviewed. Findings include: 1. A record review revealed the room temperature and humidity thermometer had expired and a lack of documentation of the refrigerator temperatures. Refer to D5431 A & B. 2. A lack of documentation revealed that the background counts and quality control was not performed and documented for the hematology Beckman Coulter DxH520 analyzer each day of patent testing. Refer to D5445. 3. The laboratory failed to document corrective action for improper temperature of the Lab-Line Instruments Inc. incubator used for the Group A beta hemolytic streptococcus bacteriology testing. Refer to D5785. 4. A interview on 1/04/2023 at 1:10 pm, TP #1 confirmed the above documentation was not available on the day of the survey.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to ensure the testing personnel performing the duties of a Technical Consultant, had met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's

	degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to ensure personnel performing the Technical Consultant duty of testing personnel competency assessments was qualified for 2 (TP#1 and TP#7) of 2 personnel performing competency assessments. Findings include: 1. A review of the laboratory's personnel competency records revealed for 2 (TP#1 and TP#7) of 2 personnel performing competency assessments were not qualified as a Technical Consultant as follows: a. TP#1 tested by TP#7 b. TP#2 - TP#11 tested by TP#1 c. TP#13 tested by TP#1 2. The surveyor requested the qualifications of TP#1 and TP#7 to serve as the Technical Consultant on 10:36 am and the documentation was not made available. 3. An interview on 12/28/2022 at 10:36 am, TP#1 confirmed that TP#1 and TP#7 did not have the qualifications to perform the duties of a Technical Consultant.