Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0691843	(X3) Date Survey Completed 09/18/2019
Name of Provider or Supplier Merrillwood Pediatrics Pc	**Street Address, City, State** 27332 Woodward #100, Royal Oak, 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 and interview with the Technical Consultant (TC), the laboratory failed to retain instrument raw data for quality control records and calibrations for 2 (September 2017 to September 2019) of 2 years. Findings include: 1. A record review of quality control and calibration records revealed only hand-transcribed results were available for the QBC AutoRead Plus hematology analyzer. 2. During the interview on September 18, 2019 at approximately 10:50 am, the TC confirmed only hand-transcribed results were available and the instrument did not produce printed copies.
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: The laboratory failed to meet applicable analytic system requirements and correct

	identified problems. Findings include: 1. The laboratory failed to follow the "Quality Control Policy for Hematology" when a control value falls outside the manufacturer's stated range for 9 lot numbers. Refer to D5401. 2. The laboratory quality control plan failed to 1) detect immediate errors that can occur due to quality control failures and 2) detect environmental and operator performance errors resulting in analyzer test system failures, accuracy, and precision for 9 lot numbers. Refer to D5441. 3. The laboratory failed to monitor and evaluate the analytic system assessment activities for problems and make corrections to prevent recurrence of the problems for 9 hematology quality control lot numbers. Refer to D5793.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on procedure review and interview with the Technical Consultant (TC), the laboratory failed to follow the "Quality Control Policy for Hematology" when a control value falls outside the manufacturer's stated range for 9 ("QBC Hematology Control Assay sheets" for lot numbers Q525, Q528, Q530, Q533, Q536, Q538, Q545, Q547, and Q550) of 9 lots in use during the period from 9/27/2017 to 9/10/2019 reviewed. Findings include: 1. "Quality Control Policy for Hematology" procedure review revealed "any level out of range is repeated once". 2. On September 18, 2019 at approximately 12:30 pm, the TC was informed that on multi days during the 9/27 /2017 to 9/10/2019 review revealed that both levels of controls values were outside the manufacturer ranges. There was no documentation to show control levels I and/or II had been repeated as follows: a. Q525 - hematocrit (Hct) run on November 25 and 28, 2017 b. Q528 - Hct run on February 5, 2018; platelet (Plt) run on February 10, 2018 c. Q530 - Hct run on March 13, 19, and 20, 2018; "Gran %" run on March 24, 2018 d. Q533 - Hct run on May 14, 2018 e. Q536 - Hct run on July 10, 16-20, 23-25, no date recorded, and 27, 2018; hemoglobin (Hgb) + Hct run on July 21, 2018 f. Q538 - Hct run on August 24 and 28, 2018; Hgb + Hct run on September 8, 2018 g. Q545 - Hct run on January 14-15, 18, 29 and February 1-2, 2019; Hgb + Hct run on January 19 and 26, 2019 h. Q547 - Hct run on March 1, 7-8, 13-15, and 18, 2019 i. Q550 - Hct run on April 29-30 and May 1-2, 4, 6, 9, 13-15, no date recorded, no date recorded, and 18, 2019; Hgb + Hct run on May 3 and 11, 2019 3. During the interview on September 18, 2019 at approximately 12:30 pm, the TC acknowledged controls were not repeated and documented as the policy states.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and

precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Consultant (TC), the laboratory quality control plan failed to 1) detect immediate errors that can occur due to quality control failures for the QBC Autoread Plus hematology analyzer for 9 ("QBC Hematology Control Assay sheets" for lot numbers Q525, Q528, Q530, Q533, Q536, Q538, Q545, Q547, and Q550) of 9 lots in use and 2) detect environmental and operator performance errors due to analyzer test system failures, accuracy, and precision for 9 ("QBC Hematology Control Assay sheets" for lot numbers Q525, Q528, Q530, Q533, Q536, Q538, Q545, Q547, and Q550) of 9 lots in use during the period from 9/27/2017 to 9/10/2019 reviewed. Findings include: 1. Quality Control Failures Review for 9 of 9 QBC Autoread Plus quality control (QC) lots revealed that both levels of control (Level I and II) material were outside the manufacturer ranges and only one level of control material was performed and documented as follows: a. Q525 - hematocrit (Hct) run on November 25 and 28, 2017 and Level II "Grans (%) and Lymph/Mono" were never documented on the log sheet on December 04, 2017 b. Q528 - Hct run on February 5, 2018; platelet (Plt) run on February 10, 2018 c. Q530 - Hct run on March 13, 19, and 20, 2018; "Gran %" run on March 24, 2018; and no Level I for "Lymp/Mono, Plt, WBC, % Gran, and % Lymph" was documented on March 24, 2018 d. Q533 - Hct run on May 14, 2018 e. Q536 - Hct run on July 10, 16-20, 23-25, no date recorded, and 27, 2018; hemoglobin (Hgb) + Hct run on July 21, 2018 f. Q538 - Hct run on August 24 and 28, 2018; Hgb + Hct run on September 8, 2018 g. Q545 - Hct run on January 14-15, 18, and 29 and February 1-2, 2019; Hgb + Hct run on January 19 and 26, 2019 h. Q547 - Hct run on March 1, 7-8, 11, 13-15, and 18, 2019; no Level II for "Hgb, Hct, Gran %, Lymp/Mono, Plt, WBC, % Gran, and % Lymph" was documented on March 9, 2019; and no Level I for "Hgb, Hct, Gran %, Lymp/Mono, Plt, WBC, % Gran, and % Lymph" was documented on March 11, 2019 i. Q550 - Hct April 29-30 and May 1-2, 4, 6, 9, 13-15, no date recorded, no date recorded, and 18, 2019; Hgb + Hct run on May 3 and 11, 2019 2. Environmental and Operator Performance Review of 9 of 9 QBC Autoread Plus quality control lots revealed on multi days a hematology parameter was out of manufacturer range due to system failures, operator error, accuracy, and or precision as follows: a. Q525 - Level I "Hct" - December 4, 2017 Level II "Hct" - November 20 and 29-30 and December 5-6, 8-9, 2017 Level II "Hgb + Hct" - November 27, 2017 Level II "Gran %" - December 1, 2017 and December 4, 2017 was not recorded on the log sheet Level II "Lymp/Mono" - December 4, 2017 not recorded on the log sheet b. Q528 Level I "Hct" - February 3 2018 Lever II "Hct" - January 22-27, 29 and February 1, 6, and 8-9, 2018 Level II "Gran %" - February 1-2 and 10, 2018 Level II "Hgb + Hct" - February 10, 2018 Level II "Plt" - February 2, 2018 c. Q530 Level II "Hct" - March 6-7, 10, 14, 16-17, 21, and 23, 2018 Level II "Hgb + Hct" - March 9, 2018 d. Q533 Level I "Hct + Hct" - May 21, 2018 Level II "Hct" -May 9, 11, 15-19, and 22-26, 2018 Level II "Gran %" - May 9, 2018 Level II "Plt" - May 9, 2018 Level II "Hgb" - May 16, 2018 e. Q536 Level I "Hgb" - July 20, 2018 Level I "Plt" - July 20 and 24, 2018 Level II "Hct" - July 11-13, 2018 Level II "Hgb" - July 23 and 25, 2018 Level II "Gran %" - July 21, 2018 Level II "WBC" - July 21, 2018 f. Q538 Level II "Hct" - August 20, 23, 27, 29-31, 2018 and September 5, 2018 Level II "Hgb + Hct" - September 1, 4, and 6, 2018 g. Q545 Level I "Hgb" -January 14, 2019 Level II "Hct" - January 16, 21-22, 24-25, 28, and 30-31, 2019 h. Q547 Level 1 "Hct" - March 4 and 6, 2019 Level I "Hgb, Hct, Gran %, Lymp/Mono, Plt, WBC, % Gran, and % Lymph"

	- March 11, 2019 Level II "Hct" - February 26-27 and March 2, 5, and 16, 2019 Level II "Hgb, Hct, Gran %, Lymp/Mono, Plt, WBC, % Gran, and % Lymph" - March 9, 2019 i. Q550 Level I "Hct" - May 8, 2019 Level II "Hgb" - May 1-2, 4, no date recorded, and 18, 2019 3. During the interview on September 18, 2019, the LD acknowledged that QC failed for both levels (I & II) of QC material and multiple days where environmental and/or operator failures questioned the accuracy and precision of the QBC AutoRead Plus analyzer.
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 quality control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to monitor and evaluate the analytic system assessment activities for problems and make corrections to prevent recurrence of the problems for 9 (Q525, Q528, Q530, Q533, Q536, Q538, Q545, Q547,and Q550) of 9 lots reviewed from September 27, 2017 to September 10, 2019. Findings include: 1. Quality control records revealed the laboratory did not assess and document corrective action taken when both levels of control (I & II) material on multiple days during the course of 9 lot numbers in use or when only one control material run for the daily QC. Refer to D5441 - Quality Control Failures. 2. Quality control (QC) records revealed the laboratory failed to correct problems when the QC was out of manufacturer ranges due to system failure, operator error, accuracy and or precision. Refer to D5441 Environment and Operator Performance. 3. Quality control records revealed the laboratory only ran 1 of 2 levels of controls on the following days: a. no Level II - March 9, 2019 b. no Level I - March 11, 2019 4. During the interview on September 18, 2019 the TC acknowledged the log sheets showed QC out of manufacturer ranges and pertinent data was missing information.