Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2089215	06/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Robyn Jacobson Pediatrics Pllc	3910 Northdale Blvd Ste 204, Tampa, FL	

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
D0000	An announced recertification survey was conducted on 5/18/2023 to 6/19/2023 at Robyn Jacobson Pediatrics, PLLC, clinical laboratory in Tampa, Florida. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 4:14 PM on 6/19/2023. The following Conditions were not met: D5400- Analytic Systems 493.1250 D6000- Moderate Complexity Laboratory Director 493.1403
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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, consultant competency. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report (Form CMS-209), the policy manual, personnel records, and staff interview, the laboratory failed to document an annual competency assessment for 1 Testing Person (#A) out of 2 Testing Persons for 1 (2021) of 2 years reviewed. Findings included: Review of the CMS-209, signed by the Laboratory Director on 5/16/23, revealed the Laboratory Director was also the Technical Consultant and there were two (#A, #B) Testing Personnel. Review of the laboratory's policy, Staff Orientation, Training, and Competency Assessment, stated, "After initial competency assessment at the completion of orientation and training, competency assessment will occur at 6 months, 12 months, and annually thereafter." Review of personnel records for Testing Person #A, with a hire date of 10/2016 revealed no annual competency assessment was performed in 2021. Interview with Testing Person #A on 5/18/23 at 12:15 PM confirmed she performed complete blood count (CBC) testing in Hematology and had no annual competency assessment completed in 2021.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, policy review, and interview, the laboratory failed to follow their policy for labeling specimens for complete blood count (CBC) testing for 2 out of 2 patient samples observed on 6/12/2023. Findings included: Observation of the laboratory on 6/12/2023 at approximately 1:45 PM revealed two pediatric lavender top blood collection tubes, with blood in them, in a rack on the countertop. The first tube was labeled with three letters and the second tube did not have any patient identifiers on it. Review of the laboratory's policy titled "Specimen Collection, Handling and Transport; Patient Test Management" revealed: "3. Specimen collection personnel will:...Label specimens with patients name and one other unique identifier... Requirements for acceptable specimens: Testing will ONLY be performed when the minimum identification criteria is met. Specimens must be accessioned, (identified and logged); properly labeled with the patient's complete name and secondary identifier, date and time of collection, and initials of the phlebotomist." Review of the laboratory policy titled "BLOOD COLLECTION: CAPILLARY PUNCTURE 13. Match the specimens to the patient and label all of the tubes immediately AFTER completion of the filling of the collection tubes. All tubes are labeled with a minimum of two unique identifiers. Information to be included on the label is: a. Patient's first and last names b. Patient's secondary identifier (determined by the facility) c. Date and time of collection d. Initials of the phlebotomist NOTE: The small size of these tubes limits the amount of information that can be included. Minimally include the patient's name and date." During an interview on 6/12/2023 at 2:00 PM, Testing Person #A confirmed the blood collection tubes were not labeled properly per their policy.
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 review of manufacturers' package inserts, Levey Jennings reports, Quality Control (QC) printouts, patient printouts and interview, the Laboratory failed to ensure expired QC material was not used prior to patient testing (See D5417), failed to follow their QC Policy running three levels (Low, Normal, High) of QC for complete blood counts (CBCs) before patient testing (See D5441), failed to ensure

	QC material for Complete Blood Counts (CBCs) met the laboratory's acceptable criteria before reporting patient test results.(See D5481), failed to take corrective action when quality control was not in range (See D5783), and failed to perform Quality Assurance activities to identify problems in the laboratory (See D5793).
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: Based on review of the manufacturers' Quality Control (QC) package insert, QC record printouts, and staff interview, the laboratory failed to ensure expired QC material was not used prior to patient testing for Complete Blood Counts (CBCs) for 59 of 172 days of testing reviewed from February 2022 to June 2023. Findings included: Review of the manufacturers' QC package insert revealed three levels: Sysmex e-Check control material, low, normal, and high. Review of QC record printouts revealed: Low, normal, and high control material lot# 13060712, with an expiration date of 2/09/22 were run on 2/10/22, 2/11/22, 2/14/22, 2/15/22, 2/16/22, 2 /17/22, 2/18/22, 2/22/22, 2/23/22, and 2/24/22. 22 patients were reported during this time. Low, normal, and high control material, lot# 20250712 with an expiration date of 5/04/22 were run on 5/06/22, 5/09/22, 5/10/22, 5/11/22, 5/12/22, 5/13/22, 5/23/22, 5 /24/22, 5/25/22, 5/26/22, 5/27/22, 5/31/22, 6/01/22, 6/02/22, 6/06/22, 6/07/22, 6/08 /22, 6/10/22, 6/13/22, 6/14/22, 6/15/22, 6/16/22, 6/17/22, 6/20/22, 6/21/22, 6/22/22, 6 /23/22, 6/24/22, 6/28/22, 6/29/22, 6/30/22, 7/01/22, 7/05/22, 7/06/22, 7/07/22, 7/08 /22, 7/11/22, 7/13/22, 7/14/22, 7/18/22, and 7/19/22. 87 patients were reported during this time. Low, normal, and high control material, lot #21090710 with an expiration date of 7/27/22 were run on 7/28/22, 7/29/22, and 8/01/22. 7 patients were reported during this time. Low, normal, and high control material, lot #21930712 with an expiration date of 10/19/22 were run on 10/20/22, 10/21/22, 10/27/22, and 10/28/22. 5 patients were reported during this time. Low, normal, and high control material, lot #22770710 with an expiration date of 1/11/23 were run on 1/24/23. 3 patients were reported during this time. Interview with Testing Person #A on May 18, 2023 at 2:00 PM confirmed five different lot numbers with three levels of quality control each, were used after their expiration dates during which 124 patient results were reported.
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 review of the policy manual, Quality Control (QC) reports, patient test printouts, and interview, the laboratory failed to follow their QC Policy running three levels (Low, Normal, High) of QC for complete blood counts (CBCs) before patient testing was reported for 23 days in 2022 and 4 days in 2023 from February 2022 to June 2023 for a total of 74 patients. Findings included: Policy review of "Hematology (SYSMEX XP-300)" stated: "1. Run all three levels of the Sysmex e-Check control material, low, normal, and high to monitor the performance of the analyzer and reagent. 2. Quality control should be run in the morning after performance of daily maintenance and before any patient testing is initiated." Review of QC reports and patient test printouts revealed that patients were reported before QC was performed on the following days: On 5/09/22 one patient was run at 8:16 AM, low level QC was run at 1:30 PM, normal level QC was run at 2:25 PM, and high level QC was run at 2:27 PM. On 5/11/22 patients were run at 10:24 AM and 11:07 AM. Low level QC was run at 2:27 PM, normal level QC was run at 2:20 PM, and high level QC was run at 2:22 PM. On 5/12/22 patients were run at 8:43 AM and 9:56 AM. Low level QC was run at 3:37 PM, normal level QC was run at 3:42 PM, and high level QC was run at 3:45 PM. On 5/23/22 patients were run at 9:08 AM and 9:44 AM. Low level QC was run at 1:24 PM, normal level QC was run at 1:25 PM, and high level QC was run at 1:27 PM. On 5/24/22 one patient was run at 10:40 AM. High level QC was run at 12:38 PM, normal level QC was run at 3:09 PM, and low level QC was run at 3:37 PM. On 5 /25/22 one patient was run at 9:40 AM. High level QC was run at 4:28 PM, normal level QC was run at 4:29 PM, and low level QC was run at 4:31 PM. On 5/26/22 patients were run at 9:13 AM, 10:21 AM, 10:39 AM, and 11:03 AM, High level QC was run at 3:16 PM, normal level QC was run at 4:16 PM, and low level QC was run at 5:21 PM. On 5/27/22 one patient was run at 10:05 AM. High level QC was run at 3: 18 PM, normal level QC was run at 3:26 PM, and low level QC was run at 4:09 PM. On 6/01/22 one patient was run at 10:45 AM, Low level QC was run at 2:43 PM, normal level QC was run at 2:45 PM, and high level QC was run at 4:11 PM. On 6/02 /22 patients were run at 8:48 AM, 9:27 AM, 9:35 AM, and 10:41 AM. Low level QC was run at 11:10 AM, normal level QC was run at 11:11 AM, and high level QC was run at 11:13 AM. On 6/06/22 patients were run at 9:29 AM, 11:02 AM, and 11:05 AM. Low level QC was run at 2:28 PM, normal level QC was run at 2:45 PM, and high level QC was run at 10:58 AM. On 6/07/22 patients were run at 9:11 AM and 11: 24 AM. Low level QC was run at 2:45 PM, normal level QC was run at 3:07 PM, and high level QC was run at 3:09 PM. On 6/08/22 patients were run at 8:40 AM, 9:14 AM, and 10:14 AM. Low level QC was run at 10:21 AM, normal level QC was run at 12:12 PM, and high level QC was run at 2:01 PM. On 6/10/22 patients were run at 9: 05 AM, 10:17 AM, and 11:20 AM. Low level QC was run at 11:27 AM, normal level QC was run at 11:51 AM, and high level QC was run at 2:40 PM. On 6/13/22 patients were run at 9:16 AM, 9:18 AM, 10:38 AM, and 11:59 AM. Low level QC was run at 5:16 PM, normal level QC was run at 5:17 PM, and high level QC was run at 5:19 PM. On 6/15/22 one patient was run at 11:10 AM. Low level QC was run at 5:23 PM, normal level QC was run at 5:21 PM, and high level QC was run at 5:18 PM. On 6/16 /22 patients were run at 8:48 AM, 10:14 AM, and 10:53 AM. Low level QC was run at 10:58 AM, normal level QC was run at 11:19 AM, and high level QC was run at 11: 24 AM. On 6/17/22 patients were run at 8:54 AM, 9:39 AM, and 10:19 AM. Low level QC was run at 10:21 AM, normal level QC was run at 11:04 AM, and high level QC was run at 11:43 AM. On 6/20/22 patients were run at 9:36 AM and 11:19 AM. Low level QC was run at 5:15 PM, normal level QC was run at 5:17 PM, and high level QC was run at 5:21 PM. On 6/21/22 patients were run at 9:35 AM and 11:47 AM. Low level QC was run at 1:42 PM, normal level QC was run at 1:43 PM, and

	high level QC was run at 1:45 PM. On 6/22/22 patients were run at 8:58 AM, 9:10 AM, and 9:56 AM. Low level QC was run at 10:16 AM, normal level QC was run at 10:17 AM, and high level QC was run at 10:19 AM. On 7/19/22 patients were run at 8:36 AM and 10:18 AM. High level QC was run at 12:41 PM, normal level QC was run at 12:43 PM, and low level QC was run at 12:44 PM. On 8/01/22 patients were run at 8:37 AM and 10:07 AM. Low level QC was run at 12:11 PM, normal level QC was run at 1:38 PM, and high level QC was run at 1:40 PM. On 1/24/2023 patients were run at 10:46 AM, 11:03 AM, and 11:13 AM. Low level QC was run at 1:04 PM, normal level QC was run at 1:30 PM, and low level QC was run again at 4:09 PM. On 3/21/23 patients were run at 10:00 AM, 10:30 AM, 11:00 AM, and 11:30 AM. Low level QC was run at 3:35 PM, normal level QC was run at 3:24 PM, and high level QC was run at 2:43 PM. On 3/28/23 patients were run at 9:30 AM, 10:30 AM, and 11:00 AM. Low level QC was run at 11:26 AM, normal level QC was run at 11:06 AM, and high level QC was run at 11:05 AM. On 3/29/23 patients were run at 8:30 AM, 9:00 AM, 9:30 AM, 10:00 AM, 10:30 AM, and 11:00 AM. Low level QC was run at 3:55 PM, normal level QC was run at 3:54 PM, and high level QC was run at 3:52 PM. On 5/22/23 patients were run at 8:30 AM, 9:00 AM, 9:30 AM, 10:30 AM, 11:00 AM, and 11:30 AM. High level QC was run at 3:02 PM, normal level QC was run at 3:05 PM, and low level QC was run at 3:06 PM. Interview with the Laboratory Director on 6/12/2023 at 2:45 PM confirmed QC was run after patients were tested and reported.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the policy manual, test menu, Levey Jennings Charts, Quality Control (QC) printouts, and interview, the laboratory failed to ensure QC material for Complete Blood Counts (CBCs) met the laboratory's acceptable criteria before reporting patient test results for 30 days of 195 days reviewed from February 2022 to June 2023. Findings include: Review of the laboratory's QC policy revealed: "Three Control Protocol: 1. Accept the run if: a. All levels are within 2 SD of the established mean b. One level is between 2 SD and 3 SD and the other two levels are within 2 SD of the established mean, for that run only (1-2S) 2. Reject the run if: a. All levels are outside of 2 SD of the established mean b. Two of three levels are outside of 2 SD (2 of 3-2S) c. The same level is out of 2 SD and within 3 SD on two consecutive runs (2-2S) 3. If the run is rejected: a. Rerun the controls. If they are still outside acceptable limits, open fresh controls and rerun. If the controls are within limits, run and report patient test results. 4. If the run is rejected: a. Rerun the controls. If they are still outside acceptable limits, open fresh controls and rerun. If the controls are within limits, run and report patient results. b. If after rerun, the controls are out of acceptable limits, check the following variables: expiration date of reagents, change in lot numbers of controls or reagents, date of last calibration, and maintenance procedures. c. If control values are still unacceptable, troubleshoot according to the manufacturer's guidelines. d. If the situation persists, do not run patient samples. Send specimens to the appropriate reference laboratory, according to the patient's insurance carrier's stipulations. e. When the situation is corrected and controls are again acceptable, patient testing may resume and results may be reported. Always document any corrective action taken on the Corrective Action Log for follow-up review." Review

	of the laboratory's test menu revealed the following analytes: White Blood Count (WBC), Red Blood Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Platelet Count (PLT), Lymphocyte Percentage (LYM%) and Absolute count (LYM#), Monocytes/mixed Percentage (MXD%) and Absolute count (MXD#), Neutrophil Percentage (NEUT%) and Absolute count (NEUT#), Red Cell Distribution Width Coefficient of Variation (RDW-CV) and Standard Deviation (RDW-SD), and Mean Platelet Volume (MPV). Review of Levey Jennings Charts and QC printouts for the Sysmex XP-300 revealed the following dates QC was out of range: 1. On 2/23/22 the WBC and HGB for the low, normal, and high control were out of acceptable range. The MCH, MCHC, LYM#, MXD#, and NEUT# for the normal and high control were out of acceptable range. (3 patients reported) 2. On 2/24/22 the MXD# and NEUT# for the low and high control were out of acceptable range. (2 patients reported) 3. On 5/09/22 the WBC, RBC, HGB, HCT, LYM#, PLT, and LYM#, MXD#, and NEUT# for the low, normal, and high control were out of acceptable range. (1 patient reported) 4. On 5/11/22 HGB was out for the normal and high control. (2 patients reported) 5. On 5/23/22 and 5/24 /22 HGB was out for two consecutive days for the high control. (1 patient reported) 6. On 5/25/22, 5/26/22, 5/27/22, and 5/31/22 PLT was out for four consecutive testing days in a row for the low control. (4 patients reported 5/26/22, 1 patient reported 5/27 /22, 2 patients reported 6/1/22) 7. On 5/31/22 and 6/1/22 HGB was out for the low control. (1 patient reported on 6/1/22) 8. On 6/2/22 PLT was out of range for the low and high control. (4 patients reported) 9. On 6/6/22 WBC, RBC, HGB, HCT, PLT, and NEUT# were out for the low, normal and high control. LYM% was out of range for the low and normal control. (3 patients reported) 10. On 6/6/22, 6/7/22, and 6/8/22 WBC, RBC, HGB, HCT, LYMPH% and NEUT# were out of range for the low control three consecutive days in a row. (8 patients reported) 11. On 6/7/22 and 6/8/22 MXD% and NEUT% were out of range for the low control. (5 patients reported) 12. On 6/6/22 and 6/7/22 WBC, HGB, HCT, and NEUT# were out of range for the normal control. (5 patients reported) 13. On 6/6/22 and 6/7/22 RBC, HGB, and HCT were out of range for the high control. (5 patients reported) 14. On 6/10/22, 6/13/22, 6 /14/22, 6/15/22, 6/16/22, 6/17/22, 6/20/22, 6/21/22, 6/22/22, and 6/23/22 PLT was out of range for ten consecutive testing days in a row for the low control. (25 patients reported) 15. On 6/10/22 and 6/13/22 WBC and HGB were out for the low control. (7 patients reported) 16. On 6/13/22 and 6/14/22 MXD% was out for the low control. (6 patients reported) 17. On 6/17/22 HGB was out of range for the normal and high control. (3 patients reported) 18. On 8/1/22 HCT was out of range for the normal and high control. (2 patients reported) 19. On 3/17/23, 3/20/23, and 3/21/23 RBC was out of range for three consecutive testing days in a row for the high control. (7 patients reported on 3/20/23 and 4 patients reported on 3/21/23) 20. On 3/20/23 and 3/21/23 HGB was out of range for the high control. (4 patients reported on 3/21/23) Interview on 5/18/2023 at 2:45 PM with Testing Person #A confirmed she didn't know when QC was out of range.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of

	accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) Protocol, QC Corrective Action Log, and interview, the laboratory failed to take corrective action to ensure reporting of accurate and reliable patient tests when QC material failed to meet the laboratory's acceptable criteria for 50 days of 195 days reviewed from February 2022 to June 2023. Findings included: Review of the laboratory's QC Protocol revealed: "Three Control Protocol: 1. Accept the run if: a. All levels are within 2 SD of the established mean b. One level is between 2 SD and 3 SD and the other two levels are within 2 SD of the established mean, for that run only (1-2S) 2. Reject the run if: a. All levels are outside of 2 SD of the established mean b. Two of three levels are outside of 2 SD (2 of 3-2S) c. The same level is out of 2 SD and within 3 SD on two consecutive runs (2-2S) 3. If the run is rejected: a. Rerun the controls. If they are still outside acceptable limits, open fresh controls and rerun. If the controls are within limits, run and report patient test results. 4. If the run is rejected: a. Rerun the controls. If they are still outside acceptable limits, open fresh controls and rerun. If the controls are within limits, run and report patient results. b. If after rerun, the controls are out of acceptable limits, check the following variables: expiration date of reagents, change in lot numbers of controls or reagents, date of last calibration, and maintenance procedures. c. If control values are still unacceptable, troubleshoot according to the manufacturer's guidelines. d. If the situation persists, do not run patient samples. Send specimens to the appropriate reference laboratory, according to the patient's insurance carrier's stipulations. e. When the situation is corrected and controls are again acceptable, patient testing may resume and results may be reported. Always document any corrective action taken on the Corrective Action Log for follow-up review." Review of the laboratory's "Quality Control Corrective Action Log" for the XP-300 hematology analyzer, serial number A6271, revealed no entries. No corrective action was taken when quality control samples were out of acceptable range on the XP-300 hematology analyzer for the following days: 2/23/22, 2/24/22, 3/17/22, 3/22/22, 3/23/22, 3/25/22, 3/28/22, 4/4/22, 4/5/22, 4/6/22, 4/7/22, 4/8/22, 4/11/22, 4/12/22, 4/13/22, 4/14/22, 4/15/22, 4/18/22, 4/19/22, 5/2/22, 5/9/22, 5/10/22, 5/11/22, 5/23/22, 5/2422, 5/25/22, 5/26/22, 5/27/22, 5/31/22, 6/1/22, 6/2/22, 6/6/22, 6/7/22, 6/8/22, 6/10/22, 6/13/22, 6/14/22, 6/15/22, 6/16/22, 6/17/22, 6/20/22, 6/21/22, 6/22/22, 6/23/22, 7/26/22, 7/27/22, 8/1/22, 3/17/23, 3/20/23, 3/21/23. Interview on 5/18/2023 at approximately 2:00 PM with Testing Person #A confirmed no corrective action was documented when QC was out of 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 review of Quality Assurance (QA) records and interview, the laboratory failed to follow their QA Plan and perform and document QA activities to identify problems in the laboratory for 2 (2021-2023) of 2 years reviewed. Findings included:

	Review of QA Plan records revealed monthly QA worksheets with no data entries on them. Interview with Testing Person #A on May 18, 2023 at 1:00 PM confirmed no QA activities had been documented for 2021, 2022, and 2023.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of manufacturers' package inserts, Levey Jennings reports, Quality Control printouts, patient printouts, the Laboratory Personnel Report (Form CMS-209), the policy manual, personnel records, and interview, the Laboratory Director failed to maintain the Quality Control (QC) program and ensure quality laboratory services (See D6020), failed to maintain the Quality Assurance (QA) Plan (See D6021).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of manufacturers' package inserts, Levey Jennings reports, Quality Control printouts, patient printouts and interview, the Laboratory Director failed to ensure the Quality Control program was maintained since February 2022. Findings Included: The Laboratory Director failed to ensure expired QC material was not used prior to patient testing (See D5417), failed to follow their QC Policy running three levels (Low, Normal, High) of QC for complete blood counts (CBCs) before patient testing (See D5441), failed to ensure QC material for Complete Blood Counts (CBCs) met the laboratory's acceptable criteria before reporting patient test results (See D5481), and failed to perform and document corrective action when quality control was not in range (See D5783).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of Quality Assurance (QA) records and interview, the Laboratory Director failed to follow their QA Plan and perform and document QA activities to identify problems in the laboratory for 2 (2021-2023) of 2 years reviewed. Findings Included: The Laboratory Director failed to perform and document QA activities (See D5793).
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report (Form CMS-209), the policy manual, personnel records, and staff interview, the Technical Consultant failed to document an annual competency assessment for 1 Testing Person (#A) out of 2 Testing Persons for 1 (2021) of 2 years reviewed. Findings Included: The Technical Consultant failed to perform annual competency assessments on 1 out of 2 Testing Persons (See D5209).