Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2064164	04/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Priority Medical Clinic, Llc	601 North 15th Avenue, Laurel, MS	

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 review of Abbott Emerald Cell-Dyn hematology analyzer quality control (QC) records from the date of installation on 7/21/2022 through 4/25/2023, the manufacturer's assay information sheet with acceptable control ranges, and interview with the laboratory director on 4/25/2023 at 2:00 p.m., the laboratory failed to retain the manufacturer's assay information sheets for four of five lots of Abbott Cell-Dyn 18 Plus hematology controls, in use for 32 of 40 weeks reviewed. Findings include: 1. Review of Abbott Emerald Cell-Dyn hematology analyzer QC records from the date of installation on 7/21/2022 through 4/25/2023 revealed the following five lots of Abbott Cell-Dyn 18 Plus hematology controls were in use for quality control testing from 7/21/2022 through 4/25/2023: Lot #2150 was in use for 5 weeks from 7/21/2022 until 8/26/2022. Lot #2206 was in use for 5 weeks from 8/26/2022 until 9/29/2022. Lot #2234 was in use for 10 weeks from 9/29/2022 until 12/12/2022. Lot #2318 was in use for 12 weeks from 12/12/2022 until 3/2/2023. Lot #3037 was in use for 8 weeks from 3/2/2023 through 4/25/2023. 2. Review of the manufacturer's assay information sheet, with acceptable control ranges, revealed only the assay information sheet for Lot #3037, currently in use on the day of the survey, was retained. The manufacturer's assay information sheets with acceptable control ranges for Lots #2150, #2206, #2234, and #2318, in use for quality control testing for 32 of 40 weeks reviewed, were not available for review on the day of the survey, 4/25/2023. 3. In an interview on 4/25/2023 at 2:00 p.m., the laboratory director confirmed the manufacturer's assay information sheets with acceptable control ranges for Lots #2150, #2206, #2234, and #2318 were not available.

D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the six hematology proficiency testing (PT) events performed since the last survey on 8/4/2021 and interview with the laboratory director on 4/25/2023 at 2:30 p.m., the laboratory failed to retain analyzer printouts for hematology proficiency testing samples for two of the six PT events performed since 8/4/2021. Findings include: 1. Review of the hematology proficiency testing records for Events 2 and 3 of 2021, Events 1, 2, and 3 of 2022, and Event 1 of 2023 revealed the laboratory failed to retain the hematology analyzer printouts for Event 3 of 2021 and Event 2 of 2022 (2 of 6 events). 2. In an interview on 4/25/2023 at 2:30 p.m., the laboratory director confirmed hematology analyzer printouts for Proficiency Testing Event 3 of 2021 and Event 2 of 2022 were not retained.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual, the Abbott Cell-Dyn Emerald Operator's Manual, patient complete blood count (CBC) test results from 2/1/2023 through 2/15/2023, and interview with the laboratory director on 4/25/2023 at 1:30 p.m., the laboratory failed to establish written procedures for the verification of CBC results when 11 of 147 patient CBC results reviewed were flagged by the Cell-Dyn Emerald hematology analyzer for white blood (WBC) differential abnormalities or platelet abnormalities. Findings include: 1. The Abbott Cell-Dyn Emerald Operator's Manual states for WBC Flags L1, L2, L3, L5, "Follow your laboratory's review criteria or review a stained smear to confirm the differential results." The Operator's Manual states for Platelet Flags P1, P2, P3, "Review a stained smear to determine the cause and confirm the platelet count." 2. Review of patient CBC test results from 2/1/2023 through 2/15/2023 revealed the following 11 patient

	CBC results, of 147 patient CBC results reviewed, were flagged for WBC differential or platelet abnormalities: 2/3/2023--Patient #11518--L3 flag. 2/6/2023--Patient #11807--L3 flag. 2/7/2023--Patient #11403--L3 and P2 flags. 2/8/2023--Patient #10466--L3 flag. 2/10/2023--Patient #7842--L1 flag. 2/13/2023--Patient #229--L3 flag; Patient #6238--L1 flag; Patient #1745--L3 flag. 2/15/2023--Patient #11610--L3 and P2 flags; Patient #9903--L3 flag; Patient #4011--L3 flag. 3. Review of the laboratory's policies and procedures manual revealed there was no policy for verifying CBC results flagged by the Abbott Cell-Dyn Emerald hematology analyzer for WBC differential or platelet abnormalities. 4. In an interview with the laboratory director on 4/25/2023 at 1:30 p.m., the laboratory director stated there was no policy for verifying CBC results flagged by the Abbott Cell-Dyn Emerald hematology analyzer.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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. This STANDARD is not met as evidenced by: Based on review of the six hematology proficiency testing events performed since the last survey on 8/4/2021, lack of documentation of corrective action for a score of 0% for white blood cell (WBC) differential for Event 2 of 2022, and interview with the laboratory director on 4/25/2023 at 2:30 p.m., the laboratory director failed to ensure that an approved corrective action plan was followed when proficiency testing results were found to be unsatisfactory on 1 of 6 WBC differential assays. Findings include: 1. Review of the hematology proficiency testing scores for Events 2 and 3 of 2021, Events 1, 2, and 3 of 2022, and Event 1 of 2023 revealed a score of 0% for WBC differential for Event 2 of 2022 (1 of 6 WBC differential assays). 2. There was no documentation of corrective action for the unsatisfactory score of 0% for WBC differential for Event 2 of 2022 available for review on the day of the survey, 4/25 /2023. 3. In an interview on 4/25/2023 at 2:30 p.m., the laboratory director confirmed there was no documentation of corrective action for the unsatisfactory score of 0% for WBC differential for Proficiency Testing Event 2 of 2022.