Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1081456	03/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Priority Care, Llc	5751 Bradford Hicks Dr, Livingston, TN	

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 observation of the laboratory, review of laboratory records, review of laboratory policy, and staff interview, the laboratory failed to retain urinalysis quality control (QC) records in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 03/06/2024 at 08:15 am revealed the following equipment in use for patient urinalysis testing: - McKesson Consult Diagnostics 120 Urine Analyzer (Serial Number: 197T10077E1). - Consult Diagnostics 10SG Urine Reagent Strips (Lot: URS3030143) for urine chemistry analysis. - Axiostar Plus Microscope (Serial Number: 3108013850) for urine microscopic analysis. 2. A review of the laboratory's records revealed no documented QC for urinalysis testing in 2022, 2023, and 2024. 3. A review of the laboratory's "Quality Assessment" policy revealed the following statement under item 11. Quality Control: - "We document the results of all controls and will take appropriate actions when the controls do not perform as expected." 4. An interview with the laboratory director and lead testing person on 03/06/2024 at 12: 15 pm confirmed that the laboratory did not maintain QC records in 2022, 2023, and 2024 for urinalysis testing.
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 observation of the laboratory, review of quality control (QC) records, lack of corrective action documentation, review of laboratory policies, and staff interviews, the laboratory failed to follow its policy for documenting corrective actions for unacceptable complete blood count (CBC) QC performance (1 of 5 lots reviewed). The findings include: 1. Observation of the laboratory on 03/06/2024 at 08:15 am revealed a Horiba Micros 60 (Serial Number: 711CS97666) in use for patient CBC testing. 2. A random review of Horiba QC records revealed unacceptable performance for one level of Minotrol-16 (Lot: MX433 Level: low) CBC QC on 01/18/2022 and 01 /20/2022. 3. The laboratory could not provide corrective action documentation for the unacceptable QC performance occurring on 01/18/2022 and 01/20/2022. 4. A review of the laboratory's "Quality Control" policy revealed the following statement: - "Anytime quality control results are unacceptable, corrective actions are completed and controls retested before patient specimens are tested. All these actions are documented. All quality control, corrective action, and calibration documentation will be kept for a minimum of two years." 5. An interview with the laboratory director and lead testing person on 03/06/2024 at 12:15 pm confirmed that the laboratory did not have corrective action documentation for the unacceptable CBC QC performance on 01/18/2022 and 01/20/2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of laboratory records, and staff interview, the laboratory failed to perform and document calibration verification of the Horiba Micros 60 complete blood count (CBC) instrument at least once every six months in 2023 (two of four calibration periods reviewed). The findings include: 1. Observation of the laboratory on 03/06/2024 at 08:15 am revealed a Horiba Micros 60

	(SN: 711CS97666) in use for patient CBC testing. 2. A review of the laboratory's 2022, 2023, and 2024 instrument calibration records revealed no documented calibration of the Horiba Micros 60 in 2023. 3. An interview with the laboratory director and lead testing person on 03/06/2024 at 12:15 pm confirmed the laboratory did not have documentation for calibrating the CBC analyzer in 2023.