

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1081456	<b>(X3) Date Survey Completed</b>  07/30/2021
<b>Name of Provider or Supplier</b>  Priority Care, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records and interview with Laboratory Supervisor the laboratory failed to rotate all 8 testing persons listed on the Center for Medicare Medicaid (CMS) 209 form performing PT in 2019, 2020 and 2021. The findings include: 1. A review of the PT records for 2019, 2020 and 2021 revealed only three of the eight testing personnel's signature on the attestation sheets. 2. An interview with the Laboratory Supervisor at approximately 10:30A.M. on July 30,2021 confirmed the laboratory failed to rotate 5 of the 8 testing personnel for PT samples for 2019, 2020 and 2021.</p>
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p>

This STANDARD is not met as evidenced by:  
Based on review of the Proficiency Testing (PT) Records and interview with the Laboratory Supervisor it was determined the laboratory failed to maintain copies of the instrument printouts for PT events for 2019, 2020 and 2021. The findings include:  
1. Review of the PT records for 2019, 2020 and 2021 the laboratory failed to maintain copies of instrument printouts. 2. Interview with the Laboratory Supervisor on July 30, 2021 at 10:30A.M. confirmed the laboratory failed to maintain copies from instrument printouts for PT events in 2019, 2020 and 2021.

**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 review of the laboratory procedure manual and upon interview with the Laboratory Supervisor determined the laboratory failed to include procedures and policies for urine microscopic testing, wet preps for KOH, manufacturers package inserts, critical values and specimen rejection criteria for 2019, 2020 and 2021. The findings include: 1. Based on review of laboratory procedure manual revealed no polices or procedures for urine microscopic testing, wet preps for KOH, manufactures package inserts, critical values and specimen rejection criteria. 2. An interview at 10:00A.M. on July 30, 2021 with the Laboratory Supervisor, confirmed the laboratory procedures and policies failed to include urine microscopic testing, wet preps for KOH, manufacturers package inserts, critical values, and specimen rejection criteria for 2019, 2020 and 2021.

**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 the observation, during a laboratory tour, review of the Centers for Medical, Medicare Services (CMS) 116 form, specialties volumes and interview with Laboratory Supervisor, the laboratory failed to discard expired Potassium Hydroxide (KOH) reagent in 2019,2020 and 2021. The findings include: 1. An observation of a bottle of KOH solution currently in use while touring laboratory on survey July 30, 2021 at 9:00am, revealed the solution expired on 11/30/2019. 2. Review CMS 116 form, specialties test volumes revealed 11 patients had KOH tests performed in 2019,2020 through July 30,2021 on KOH reagent expired on 11/30/2019. 3. An interview with the Laboratory Supervisor at 9:00am on July 30, 2021 confirmed the bottle of KOH solution expired on 11/30/2021 had been used for patient testing in 2019,2020 and 2021.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the personnel records and interview with the Laboratory Supervisor the Technical Consultant failed to document 8 out of 8 testing personnel competencies in 2019,2020 and 2021 The findings include: 1. Review of the competency assessment records for testing personnel, eight out of eight testing personnel failed to have a documented review by the Technical Consultant for 2019,2020 and 2021. 2. Interview with the Laboratory Supervisor on July 30, 2021 at 10:00 A.M. confirmed the Technical Consultant failed to document competency assessments on eight out of eight testing personnel in 2019, 2020 and 2021.