

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0315624	<b>(X3) Date Survey Completed</b> 03/04/2020
<b>Name of Provider or Supplier</b> Prime Care Medical-Henderson	<b>Street Address, City, State</b> 426 White Avenue, Henderson, 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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, laboratory records, and interview with testing personnel number one, the laboratory failed to retain intermittent patient test records for at least two years in 2018, 2019, and 2020. The findings include: 1) Observation of the laboratory on March 4, 2020 at 8:15 a.m. revealed a microscope in use for patient testing for urine microscopy and wet preps. 2) Review of patient numbers five, six, seven, eight, nine and ten revealed patient testing for both urine microscopic and wet prep performed in 2018, 2019, and 2020. 3) Review of laboratory records revealed no retention of the paper used for recording the results of the urine microscopic and wet prep prior to entering the results into the laboratory electronic medical record. 4) Interview with the lead testing personnel on March 4, 2020 at 8:35 a.m. confirmed the laboratory failed to retain all analytic records for at least two years in 2018, 2019, and 2020.</p>
<b>D5793</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(b)(c)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment plan, laboratory records and interview with the technical consultant, the laboratory's quality assessment process was ineffective when it failed to correct problems in 2018, 2019 and 2020. The findings include: 1) Review of the laboratory's quality assessment plan revealed the laboratory quality assurance plan is designed to detect, control and prevent errors. 2) Review of laboratory records revealed the following errors that went undetected by review processes with no documented corrective action: The refrigerator used for storage of complete blood count (CBC) controls had temperatures documented outside the manufacturer stated storage range in 2019 and 2020. The forms used for documenting the temperatures did not have a temperature range indicated. Proficiency testing performance evaluation report for 2019 event three had a score of 80% for leukocyte count with no corrective action performed. The target limit for platelet count for calibrator lot 4756 was incorrect. Calibration was performed on December 7, 2018. CBC controls, temperature records and patient number eleven test report were performed by a person with no documented training and competency assessment. The quality control ranges for red blood cell (RBC) were incorrect for lot 069300 (current lot). Maintenance, calibration, quality control, and proficiency testing records had been reviewed by the technical consultant with no corrective actions performed. 3) Interview with the technical consultant on March 4, 2020 at 12:30 p.m. confirmed the laboratory's quality assessment process was ineffective when it failed to detect and correct problems with improper storage of complete blood count controls, unacceptable proficiency testing scores, incorrect target limits for calibrator, and incorrect quality control ranges in 2018, 2019, and 2020.