

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1023943	(X3) Date Survey Completed 01/23/2018
Name of Provider or Supplier Riverwoods Urgent Care	Street Address, City, State 280 W River Park Dr, Ste 120, Provo, UT	
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
D3029	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2)</p> <p>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and confirmation by staff, the laboratory failed to document the dates of discontinuing use for 2 of 2 past complete blood count test systems, the Abbot Emerald and Coulter AcT Diff 2 cell count analyzers. The laboratory performed approximately 5 complete blood count tests per day Findings include: 1. The laboratory replaced the Emerald in 2017 with the ABX micros 60 cell counter. 2. The laboratory procedure for the Emerald failed to include the discontinued use date. 3. The laboratory replaced the Coulter AcT Diff 2 with the Abbott Emerald cell counter (more than 2 years ago). The date the laboratory discontinued Coulter use was not recorded. 4. In an interview conducted on 01/23 /2018 at approximately 2:30 P.M. staff confirmed the discontinued date was not recorded for the Emerald cell counter and confirmed the AcT Diff 2 analyzer was discontinued for more than 2 years but the procedure remained in the manual with out a discontinued date.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to verify test accuracy for microscopic analysis of urine and vaginal specimens at least twice annually. The laboratory performed approximately 300 tests per year. Findings include: 1. A Proficiency test records review demonstrated the laboratory failed to achieve successful performance for microscopic urinalysis (UA) and vaginal wet prep and potassium hydroxide (KOH) preparations twice annually in 2017 as scores from the American Academy of Family Physicians (AAFP): Event "A" for urinalysis were 50 % and 0% for KOH and wet preparations; Event (B) of 2016 the laboratory scored 0% for UA and wet prep; and the third event of 2016 (C) the laboratory self scored the result 0% for UA and KOH. B. Proficiency test records reviewed from AAFP in 2016 documented the laboratory did not receive urinalysis and vaginal KOH and wet preparation samples for participation as follows: Event (A) resulting in scores of 0% due to no kit received. Event (C) The third event of 2016 the laboratory failed Urinalysis 0% and Wet preparation challenges 0%. 2. The laboratory failed to document it could accurately identify cells, casts and crystals in urine specimens and the presence or absence of Clue Cells, yeast and parasites in vaginal specimens twice annually in 2016 and 2017. 3. In an interview conducted on 01/23/2018 at approximately 2:30 P.M., staff confirmed the laboratory did not document test accuracy for UA, KOH and wet prep testing at least twice annually in 2016 and 2017.

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 direct observation, patient test records review, and confirmation by staff, the laboratory failed to ensure 1 of 4 reagents reviewed (potassium hydroxide) was not used past its expiration date. Findings include: 1. Potassium Hydroxide (KOH) observed expired on 04/16/2017. 2. Patient test records review included documentation the laboratory performed a KOH preparation on 01/18/2018 for patient #4757. 3. In an interview conducted on 01/23/2018 at approximately 2:45 P.M. staff confirmed the KOH had been used after the expiration date.