

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0704038	(X3) Date Survey Completed 11/06/2018
Name of Provider or Supplier Alpine Healthcare Center	Street Address, City, State 298 Main St, Keene, NH	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on record review and staff interview, the laboratory failed to follow manufacturer's instructions for performing waived complexity prothrombin (PT) / international normalized ratio (INR) testing in October 2018. Findings include: 1) Review on 11/6/2018 of a Recall for Product Correction notification by the manufacturer from August 2018 revealed "Coaguchek XS PT" test strips (PT test strips) were safe to use for INR from 0.8 to 4.5. INRs above 4.5 should be compared with another laboratory method. The recall notice stated lot numbers of "Coaguchek XS PT" test strips affected by this recall are 272167 through 334498 (the first six digits of eight total in the lot number). 2) Review on 11/6/2018 of the laboratory's procedure titled "PT/INR Testing With Coaguchek XS and XS Plus Monitoring System" last revised 7/1/2015 revealed the laboratory's reportable range for INR was 0.8 - 8.0 and failed to provide instruction to repeat and/or send out a specimen for confirmation testing at a reference laboratory when INR results are greater than 4.5. There was no indication in the procedure that it had been modified or addressed the manufacturer's recall notice from August 2018. 3) Review of six patient records from 10/4/2018 through 11/1/2018 revealed 18 INR tests performed. On 10/14/2018, one of 18 INRs was reported as 7.6. There was no documentation that a specimen was drawn and sent out to another laboratory for confirmation. Patient test results could not be traced back to what PT test strip lot number was used for testing. 4) Review on 11/20/2018 of all three bottles of PT test strips revealed all three bottles were opened and were lot numbers affected by the manufacturer's recall notice from August 2018 and used to test patients from 10/4/2018 through 11/1/2018. 5) Interview with the</p>

laboratory director (LD) on 11/2/2018 at 1:00 p.m. confirmed a specimen was not collected and sent out for testing at a reference laboratory for the 7.6 INR result obtained on 10/14/2018. The LD revealed the patient with a 7.6 INR result had been treated with vitamin K. The LD further revealed that the laboratory did not receive the manufacturer's August 2018 recall notification. B. Based on record review and staff interview, the laboratory failed to follow manufacturer's instructions for cleaning /disinfecting a patients' finger prior to collection of capillary specimen used for performing waived complexity prothrombin (PT) / international normalized ratio (INR) testing in October and November 2018. Findings include: 1) Review on 11/6 /2018 of the package insert for "CoaguChek XS PT Test" reagent test strips revealed instruction after washing or disinfecting the patient's finger to "Allow the patient's finger to dry completely before performing the fingerstick." 2) Review on 11/6/2018 of the laboratory's procedure titled "PT/INR Testing With Coaguchek XS and XS Plus Monitoring System" last revised 7/1/2015 revealed instruction to "Wipe the site with alcohol pad and wipe dry with gauze pad." 3) Interview with the laboratory director on 11/6/2018 at 1:00 p.m. confirmed the above findings and revealed the laboratory's practice was to wipe the finger dry with a non-sterile gauze pad prior to performing the fingerstick. 4) The laboratory performed 18 INR tests from 10/4/2018 through 11/1 /2018.