

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2167941	(X3) Date Survey Completed 10/31/2019
Name of Provider or Supplier Wasatch Services - Utah	Street Address, City, State 3734 North 170 E, Enoch, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, patient test reports review, and interview with staff via telephone on 10/31/2019 at approximately 9:30 A.M. the director failed to approve, sign, and date the laboratory procedure manual prior to use on 07/23/2019 and for 3 of 3 months the laboratory performed cytogenetic testing. The laboratory performed approximately 2 samples each day of testing approximately 3 days per week. Findings include: 1. Patient test reports review included documentation the laboratory reported patient test results for patient 19198121307 on 07/23/2019. 2. Procedure manual review failed to document procedure manual approval by a qualified director until 10/31/2019. 3. In a telephone interview with the laboratory general supervisor on 10/31/2019 at approximately 9:30 A.M. the supervisor confirmed the laboratory lacked documentation the director approved the procedure manual prior to using the manual in July of 2019. The laboratory lacked documentation of director approval for the initial and current directors until the day of survey.</p>