

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0870199	(X3) Date Survey Completed 07/23/2018
Name of Provider or Supplier Saint Agnes Care	Street Address, City, State 1383 E Herndon Ave Ste 102, Fresno, CA	
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
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on request, review and the lack of documentation for competency assessments, and interview with laboratory director, for seven (7) out of seven (7) random patient sampling test results reviewed covering period from 10/10//2016 to 4/27//2018, it was determined that the laboratory technical consultant/laboratory director failed to perform and document the performance of individuals responsible for moderate complexity testing. The findings included: a. There was no documentation to show that the testing personnel were evaluated during the first six months and annually thereafter. The evaluations must include but are not limited to the following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem solving skills b. There are two (2) testing personnel (TP) listed on the CMS 209 and LAB 116 forms, one (1) TP has no documentation of competency and evaluation for the years 2016, 2017, and 2018. c. The laboratory director affirmed (7/23/2018, 1630) that no competency assessments was performed and documented by the laboratory director and or technical consultant.</p>