

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2152113	(X3) Date Survey Completed 12/20/2018
Name of Provider or Supplier Saint Vincent Physician Services, Inc	Street Address, City, State 260 Cochituate Rd, Framingham, MA	
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
D0000	An initial CLIA certification survey was conducted for Saint Vincent Physician Services, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on procedural review and interview, the laboratory failed to maintain documentation to verify that the Quality Assessment (QA) policy and procedure was followed to monitor, assess and, when indicated, correct problems identified in the postanalytic systems as evidenced by the following: A review of the laboratory procedure manual on 12/20/18 revealed that there was a QA procedure in place but the laboratory failed to document the postanalytic portion on the monthly QA log sheet. A review of monthly QA log sheets for 2018 revealed that there was no documentation of QA monitoring for three out of three months (September, October and November). The laboratory manager and the laboratory technologist confirmed by interview on 12/20/18 at 11:20 a.m. that the monthly QA was being performed but had not been documented since the lab opened three months ago.</p>