

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2101629	(X3) Date Survey Completed 03/16/2018
Name of Provider or Supplier Bach Medical Group	Street Address, City, State 17672 Cowan, Irvine, 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory patient test results reports, and interview with the laboratory director, it was determined that the laboratory test result reports failed to provide accurate sample collection times, and failed to provide the test result with proper interpretations, if applicable. The findings included; a. Review of four patient test result reports, two (IDs: 12012 and 12143) out of four reports indicated inconsistent collection times of the specimen against the client ordering records. b. The ordering form for ID 12012 indicated the specimen was collected on 03/06/2018 at 12:14 PM, while the patient test report indicated the specimen was collected on 03/06/2018 at 12:35 PM. c. The ordering form for ID 12143 indicated the specimen was collected on 03/06/2018 at 08:30, while the patient test report indicated the specimen was collected on 03/06/2018 at 11:45 AM. d. One patient, ID 11554 collected on 2/22/2018 9:00 AM, test result report indicated that a drug, Gabapetin, was detected and confirmed with an urine concentration of 52.5 ng/ml which was "Inconsistent Result" under "Status" column. e. Not all the ordering physicians provide the patient's medical history in their test ordering form. Therefore, no bases of patients' medical prescriptions could be made between consistencies of the test results and the patient urine samples collected. f. The "Inconsistent Result" or "Consistent Result" under</p>

"Status" column in the patient test report, therefore, was provided inaccurately without any clarification or disclaimer by the laboratory. g. The laboratory staff affirmed (03/16/2018 @ 13:15 PM) that the test result interpretation provided, if applicable, must reflect the consistencies of the patient medical information.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory patient test result reports, and interview with the laboratory director, it was determined that 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. The findings included: See D-5805