

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2026572	(X3) Date Survey Completed 01/21/2020
Name of Provider or Supplier Lab Genomics, Llc	Street Address, City, State 11160 Warner Ave Ste 415, Fountain Valley, 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
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 review of patient test records, laboratory's policy and procedure manual, and interview with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post analytic systems. The findings included: a. The laboratory uses the Biofire Film Array Torch molecular testing panels to detect the presence or absence of pathogenic bacteria, yeast, viruses, and parasites in urine, wounds, and upper respiratory specimens. b. The laboratory did not have a written policy or procedure for reporting abnormal test results. d. Based on the laboratory's annual declaration submitted for 2018-2019, the laboratory analyzed and reported 9,074 microbiology samples for which abnormal test results were not properly reported. e. The TC and TP affirmed on January 21, 2020 at 12:00 that the laboratory did not have a written policy or procedure for reporting abnormal test results.</p>
D6106	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on interview with the laboratory supervisor and the testing personnel on January 21, 2020 at 12:00 am, the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings include: a. The laboratory did not have a policy or procedure covering reporting of abnormal test results. See tag D5891.