

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2145028	(X3) Date Survey Completed 12/06/2018
Name of Provider or Supplier Cell Diagnostics Inc	Street Address, City, State 1737 E Washington Blvd Ste 5, Pasadena, 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 request, and the lack of the laboratory's Turn Around Time (TAT) policy and procedure, and interview with the technical supervisor, and testing personnel, the laboratory failed to establish, 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. The findings included: a. The laboratory has no documentation to show that a policy and procedure for the TAT has been established, and written. b. The following patient test results were reported on varies days: Date of Test Order: Date Reported: Receipt: 6/22/2018 GI Panel 6/24/2018 7/11/2018 Respiratory Panel 7/18/2018 9/21/2018 GI Panel & Respiratory Panel 9/27/2018 Note: Gastrointestinal (GI) Panel includes: Campylobacter, Clostridium Difficile Toxins A/B, Plesiomonas Shigelloides, Salmonella, Vibrio, Vibrio Cholerae, Yersinia Enterocolitica, Enteroggregative E. Coli, Enteropathogenic E. Coli, Shiga-Like Toxin Pro E. Coli, E. Coli 0157, Shigella/Enteroinvasive E. Coli, Cryptosporidium, Cyclospora Cayetanensis, Entamoeba Histolytica, Giardia Lamblia, Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, and Sapovirus. Respiratory Panel Includes: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Matapneumovirus, Human Rhinovirus /Enterovirus, Influenza A H2009, Influenza A H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, Bordetella Parapertussis, Chlamydia peumoniae and Mycoplasma Pneumonia. c. The technical supervisor, confirmed (12/6//2018, 1600) that the laboratory has not established, written TAT policy and procedure. Based on the</p>

organisms and viruses included in the GI and Respiratory Panels, the TAT is essential in reporting the results in a timely manner.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on request and the lack of the laboratory's policy and procedure for Turn Around Time (TAT), and interview with the technical supervisor and testing personnel, it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 5891.