

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0291120	(X3) Date Survey Completed 10/06/2020
Name of Provider or Supplier Quest Diagnostics Clinical Laboratories Inc	Street Address, City, State 4225 East Fowler Ave, Tampa, FL	
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 unannounced complaint survey, #2020014948, was conducted on 10/05/20 to 10/06/20 at Quest Diagnostics Clinical Laboratories Inc. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories. The following Conditions were cited: D3000-Facility Administration 493.1100 D6076-Laboratory Director 493.1441
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow the State of Florida Emergency Rule to report all positive and negative COVID-19 test results immediately to the Department Of Health (DOH) for 191 out of 216 Patient reports reviewed (See D3009). The failure to immediately report COVID-19 results to the DOH goes back to 04/25/20. The volume of COVID-19 tests conducted from 04/01/20 to 09/30/20 was 148,463.</p>
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview the laboratory failed to follow the State of Florida Emergency Rule to report all positive and negative COVID-19 test results immediately to the Department of Health (DOH) for 191 out of 216 Patient reports reviewed. Findings Included: Review of the State of Florida Emergency Rule 64DER20-26 (64D-3.029) published 4/14/20 revealed that all positive and negative COVID-19 test results need to be reported immediately. According to 64D-3.029 Diseases or Conditions to be Reported, "Immediately" is defined as "Reportable condition of urgent public health importance. Report without delay upon the occurrence of any of the following: an indicative or confirmatory test, findings indicative thereof, or diagnosis. Reports that cannot timely be made during the County Health Department business day shall be made to the County Health Department after hours duty official." Interview via phone on 10/05/20 at 12:00 PM with the Senior Director of Operations revealed that an original issue of patients not being reported to the DOH (72,000 Patient reports from 04/25/20 to 08/29/20) was due to the results being held in a separate queue for missing patient phone number or address. She confirmed that this queue was now correct. A review of 210 Patients reported to DOH between 9/24/20 and 10/2/20 revealed 80 Patients were reported to the DOH greater than 1 day after testing: 1- Patient tested on 09/15/20 and reported to the DOH on 09/24/20. 2- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 3- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 4- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 5- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 6- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 7- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 8- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 9- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 10- Patient tested on 09/11/20 and reported to the DOH on 09/24/20. 11- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 12- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 13- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 14- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 15- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 16- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 17- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 18- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 19- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 20- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 21- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 22- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 23- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 24- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 25- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 26- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 27- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 28- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 29- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 30- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 31- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 32- Patient tested on 09/22/20 and reported to the DOH on 09/24/20. 33- Patient tested on 09/28/20 and reported to the DOH on 10/02/20. 34- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 35- Patient tested on 09/28/20 and reported to the DOH on 10/02/20. 36- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 37- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 38- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 39- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 40- Patient tested on 09/26/20 and reported to the DOH on 10/02/20. 41- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 42- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 43- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 44- Patient tested on 09/30/20 and reported to the DOH on 10/02/20.

/02/20. 45- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 46- Patient tested on 09/28/20 and reported to the DOH on 10/02/20. 47- Patient tested on 09/28/20 and reported to the DOH on 10/02/20. 48- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 49- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 50- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 51- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 52- Patient tested on 09/28/20 and reported to the DOH on 10/02/20. 53- Patient tested on 09/29/20 and reported to the DOH on 10/02/20. 54- Patient tested on 09/28/20 and reported to the DOH on 10/02/20. 55- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 56- Patient tested on 09/29/20 and reported to the DOH on 10/02/20. 57- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 58- Patient tested on 09/28/20 and reported to the DOH on 10/02/20. 59- Patient tested on 09/29/20 and reported to the DOH on 10/02/20. 60- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 61- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 62- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 63- Patient tested on 09/23/20 and reported to the DOH on 10/02/20. 64- Patient tested on 09/23/20 and reported to the DOH on 10/02/20. 65- Patient tested on 09/24/20 and reported to the DOH on 10/02/20. 66- Patient tested on 09/25/20 and reported to the DOH on 10/02/20. 67- Patient tested on 09/25/20 and reported to the DOH on 10/02/20. 68- Patient tested on 09/29/20 and reported to the DOH on 10/02/20. 69- Patient tested on 09/28/20 and reported to the DOH on 10/02/20. 70- Patient tested on 09/25/20 and reported to the DOH on 10/02/20. 71- Patient tested on 09/24/20 and reported to the DOH on 10/02/20. 72- Patient tested on 09/30/20 and reported to the DOH on 10/02/20. 73- Patient tested on 09/29/20 and reported to the DOH on 10/02/20. 74- Patient tested on 09/28/20 and reported to the DOH on 10/02/20. 75- Patient tested on 09/29/20 and reported to the DOH on 10/02/20. 76- Patient tested on 09/29/20 and reported to the DOH on 10/02/20. 77- Patient tested on 09/29/20 and reported to the DOH on 10/02/20. 78- Patient tested on 09/29/20 and reported to the DOH on 10/02/20. 79- Patient tested on 09/29/20 and reported to the DOH on 10/02/20. 80- Patient tested on 09/26/20 and reported to the DOH on 10/02/20. Interview on 10/05/20 at 5:30 PM with the Laboratory Operations Manager revealed that the QA personnel run a report of Patients not reported to the DOH. Review of this QA report from 10/05/20 revealed 6 patients were not yet reported to the DOH: 81- Patient tested on 09/29/20. 82- Patient tested on 09/30/20. 83- Patient tested on 09/30/20. 84- Patient tested on 10/01/20. 85- Patient tested on 10/01/20. 86- Patient tested on 10/01/20. Email correspondence on 10/06/20 at 2:12 PM revealed that Patient #81 was reported to the DOH on 10/05/20, Patient #82 and #83 had not been reported to the DOH, and Patient #84, #85, and #86 were reported to the DOH on 10/06/20. Review of Florida Administrative Code Rule 64D-3.031 "Notification by Laboratories" revealed that "To allow follow-up of laboratory findings suggestive of or diagnostic of diseases or conditions in the Table of Notifiable Diseases or Conditions, the form upon which the information will be reported shall be furnished by the laboratory that includes the following information: (a) The Patient's: 1. First and last name including middle initial, 2. Address including street, city, state, and zip code, 3. Phone number, including area code, 4. Date of birth, 5. Sex, 6. Race, 7. Ethnicity (specify if of Hispanic descent or not of Hispanic descent), 8. Pregnancy status if applicable, 9. Social Security number." Interview on 10/05/20 at 12:00 PM with the Senior Director of Operations confirmed that the laboratory did not have any documentation of educating collection sites to get the necessary demographic information that was causing the delayed reporting of COVID-19 results to the DOH. Review of 210 Patients reported to DOH between 9/24/20 and 10/2/20 revealed 105 Patients were reported to the DOH the day after testing: 87- Patient tested on 09/23/20 and reported to the DOH on 09/24/20. 88- Patient tested on 09/23/20 and reported to the DOH on 09

the DOH on 10/02/20. 153- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 154- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 155- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 156- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 157- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 158- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 159- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 160- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 161- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 162- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 163- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 164- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 165- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 166- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 167- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 168- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 169- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 170- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 171- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 172- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 173- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 174- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 175- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 176- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 177- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 178- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 179- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 180- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 181- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 182- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 183- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 184- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 185- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 186- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 187- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 188- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 189- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 190- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. 191- Patient tested on 10/01/20 and reported to the DOH on 10/02/20. Interview on 10/05/20 at 6:29 PM with the Laboratory Director and Laboratory Operations Manager revealed that the laboratory did not have any policies for reporting COVID-19 to the DOH and QA for monitoring the COVID-19 result reporting and corrective actions.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and staff interview the Laboratory Director failed to ensure preanalytic systems collected all required demographic information for COVID-19 reporting and failed to ensure postanalytic systems by failing to follow the State of Florida Emergency Rule to report all positive and negative COVID-19 test results immediately to the Department Of Health (DOH) for 191 out of 216 Patient reports reviewed (See D6082).

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the Laboratory Director failed to to ensure preanalytic systems collected all required demographic information for COVID-19 and failed to ensure postanalytic systems by failing to follow the State of Florida Emergency Rule to report all positive and negative COVID-19 test results immediately to the Department Of Health (DOH) for 191 out of 216 Patient reports reviewed. Findings Included: See D3009.