

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2164891	(X3) Date Survey Completed 09/29/2020
Name of Provider or Supplier Vibra Health Laboratory	Street Address, City, State 1307 Allen Drive Suite A, Troy, MI	
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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to have documented test requests for 4 (patients 56888, 65679, 66166, and 70872) of 37 patient test records reviewed. Findings include: 1. A review of patient records revealed the following patients with specimens rejected for SARS-CoV-2 testing did not have documented test requests: a. Patient 56888 b. Patient 65679 c. Patient 66166 d. Patient 70872 2. An interview on 9/29/20 at 12:28 pm with the Office Manager confirmed the laboratory did not have test requests for patients with rejected specimens.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: . The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to record the correct</p>

date specimens were received in the laboratory. Refer to D5787. 2. The laboratory failed to ensure specimens met acceptability criteria prior to reporting patients. Refer to D5787.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

. A. Based on record review and interview with the Senior Director, the laboratory failed to record the correct date specimens were received in the laboratory for 6 (April 2020 to September 2020) of 6 months. Findings include: 1. An interview with the Senior Director on 9/29/20 at 1:13 pm revealed specimens are shipped from the collection facilities overnight and are received by the laboratory the next day. 2. A review of the laboratory's patient test records revealed the following patient specimens had a gap between the collection date and the received date: a. Patients 56228, 56513, 56871, 57113, 57229, 43822, 56158, and 58579 collected on 6/30/20, received on 7/14/20. b. Patients 56513 collected on 6/30/20, received on 7/15/20. c. Patients 56874, 57067, 57101, and 57143 collected on 7/13/20, received on 7/22/20. d. Patients 56902, 56905, 56906, and 65747 collected on 7/13/20, received on 7/23/20. e. Patients 65749, 65169, 65693, 66056, and 66123 collected on 7/20/20, received on 7/28/20. 3. An interview with the Senior Director on 9/29/20 at 1:13 pm revealed the specimen received dates are recorded with the day the specimens were accessioned and not the date the laboratory received specimens. B. Based on record review and interview with the Senior Director, the laboratory failed to ensure specimens met acceptability criteria prior to reporting patients for 1 (Patient 56228) of 37 patient testing records reviewed. Findings include: 1. A review of the laboratory's stability study revealed a section stating "The results of this stability study show that there was 100% (10/10) concordance with previous results for Sputum and nasal swab specimens stored at 4-30 degrees C in UTM/UTV. There were no rerun results (invalid/inconclusive) observed during the 14 days course of this study." 2. A review of the laboratory's patient test records revealed Patient 56228 had a specimen collected on 6/30/20 and the test was performed on 7/17/20, showing more than 14 days elapsed between collection and test performance. 3. An interview on 9/29/20 at 1:13 pm with the Senior Director confirmed the laboratory exceeded the established 14 day specimen stability for the patient listed above.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Senior Director, the Laboratory Director failed to ensure quality assessment programs were maintained for COVID-19 testing for 6 (April 2020 to September 2020) of 6 months reviewed. Findings include:

1. A review of the laboratory's established "Quality Assurance Plan" procedure revealed a section stating, "Quality Assessment is a planned, ongoing review process that observes and evaluates the quality of all laboratory-related processes and activities." "Schedule quality reviews and conduct them according to the schedule, which should include monthly, quarterly, and annual review items. Data sources for monitoring and evaluating the QA program in these areas include, but are not limited to, the following: Licenses and other Administrative Documents, Specimen Collection, Accessioning/Rejection Problem Log, Corrective Action Form, Quality Control Records, Instrument Maintenance Records, Proficiency Testing Results - outside and in-house testing, In-Service and Training Records, Procedure Manual, Report data (Turnaround Time, Report Review)"
2. An interview with the Senior Director on 9/29/20 at 9:18 am revealed the turnaround time for COVID-19 testing was 24 to 72 hours.
3. A review of the patient test records revealed the following patients with testing delays:
 - a. Patient 56228 collected on 6/30/20 was reported on 7/17/20
 - b. Patients 56513, 56822, 43822, 56158, 58579, 56871, and 57113 collected on 6/30/20 were reported on 7/15/20
 - c. Patients 56874, 57067, 57101, and 57143 collected on 7/13/20 were reported on 7/27/20
 - d. Patients 56902, 56905, and 56906 collected on 7/13/20 were reported on 7/25/20
 - e. Patient 56888 collected on 7/14/20 was reported on 8/3/20
 - f. Patient 65679 collected on 7/21/20 was reported on 8/3/20
4. The surveyor requested quality assurance documentation regarding turnaround times on 9/29/20 at 11:20 am and it was not made available.
5. A review of the laboratory's "Corrective Action Report Form" from 7/12/20 revealed a section stating, "The internal control added to SARS-CoV-2 assay repeatedly failed on several consecutive runs on 7/12/20-7/13/20." A review of the "Action Taken" section stated, "Updated policy for lot to lot qualification is now enforced. In addition, a troubleshooting workflow has been discussed with the technical staff. Future issues that resemble this will pause testing of any samples requiring a 'rerun' until we resolve the problem. This will allow us to have enough sample left for retesting and provide a result to providers. Lastly, communication will be provided to our clients regarding any testing delays."
6. A review of the laboratory's letter to clients revealed it did not address testing delays. The letter had a section stating, "Due to the overwhelming demand for testing, and current quarantine measures, we will be forced to roll out our new COVID-19 test remotely. This means we will sign up and train new customers online, ship supplies directly to you, and provide clinical support and customer service via phone and email."
7. An interview on 9/29/20 at 1:20 pm with the Senior Director confirmed the laboratory did not maintain its established quality assessment programs.