Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2080648	08/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lehigh Valley Toxicology Llc	2550 Brodhead Rd, Ste 202, Bethlehem, PA	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on review of laboratory policies, RapCov rapid COVID-19 manufacturer's instructions, Laboratory Service Agreement and interview with the Managing Partner (MP), the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct problems as required in 493.1251 through 493.1283 for SARS-CoV-2 antibody testing performed from 05/07/2020 to 06/02/2020. Findings include: 1. Failure of the laboratory director to approve, sign, and date 7 of 7 procedures. Refer to D5407. 2. Failure to include external positive and negative quality control materials in the RapCov Rapid Covid 19 testing performed at the Chester County testing sites as required. Refer to D5449.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with the Managing Partner, the

	Laboratory Director (LD) failed to approve, sign, and date 7 of 7 procedures reviewed at the time of survey. Findings included: 1. On the day of survey 8/24/2020 at 10:10 am, a review of the manuals revealed the following procedures were not approved and signed by the LD prior to patient testing : - RapCov Rapid Covid 19 manual . - nCov-19 testing by RTqPCR. - Fabric Genomics Result interpretation, review, and reporting. - MiniSeq Manual(Pooling and Sequencing), Maintenance, and Troubleshooting Procedures. - Fluorescence-Based gDNA quantifications using Qubit 2.0 fluorometer. - DNA Extraction from ORAcollectDX OCD-100 swab using MAgMAx DNA Ultra 2.0 kit with KingFisher Flex. - TaqPath COVID-19 combo kit. 2. 19,418 blood samples were performed on the RapCov Rapid Covid19 kit from 5/7 /2020 to 6/2/2020. 3. The Managing Partner confirmed the findings above on 8/24 /2020 at 13:15.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation, RapCov rapid COVID-19 manufacturer's instructions, Laboratory Service Agreement (page 11), and interview with the Managing Partner (MP), the laboratory failed to include external positive and negative QC materials in the RapCov Rapid Covid 19 testing performed at the Chester County testing sites as required from 5/7/2020 to 6/2/2020. Findings Include: 1. The Laboratory Service Agreement effective May 3, 2020 between Lehigh Valley Genomics and Chester County, stated: "Laboratory shall provide Laboratory Services which shall include the use of RapCov Rapid COVID-19 Test manufactured by Advaite, (Each a 'Point of Care Test" and collectively "Point of Care test") pursuant to standing order and requisition of Chester County Health Department's Public Health Physician (the "Medical Director")". 2. The RapCov package insert states "Quality control (QC) requirements must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard QC procedures". 3. Lehigh Valley Genomics testing sites: - Longwood Gardens. - Coatesville Public Safety Training Center. 4. On the day of survey 8/24/2020, the Managing Partner could not provide QC records for the RapCov rapid COVID 19 testing performed at each testing site. 5. The laboratory could not provide the emergency use authorization for the RapCov Covid 19 test kit. 6. 19,418 patients samples where analyzed from 5/7/2020 to 6/2/2020. 7. When asked for QC records on 08/24/2020 at 12:30 p.m. the MP stated that she would provide the records within an hour. 8. Around 12:45 pm the MP asked the Lead Surveyor: " what is QC?" 9. The surveyors left the laboratory at 13:30. The MP did not provide the QC record as stated earlier. 10. During the summation at 1:30 pm, the MP was asked to provide the QC records within 24 hours. 11. On 08/25/2020 at 1:30 pm, the MP did not provide the records within 24 hours.
D5805	TEST REPORT CFR(s): 493.1291(c)

	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. This STANDARD is not met as evidenced by: Based on review of Patient Test Report and telephone conversation with the technical supervisor (TS), the laboratory failed to include on patient test reports the location and report date for the Advaite RapCov rapid COVID-19 antibody testing performed at offsite locations from 05/07/2020 to 06/02/2020 (20 of 20 patient tests reports reviewed). Finding Include: 1. The TS was contacted on 09/16/2020, to provide patient test reports (10 positive and 10 negative) for the Advaite RapCov rapid COVID-19 antibody testing performed at the Chester county offsite locations from 05 /07/2020 to 06/02/2020. 2. Lehigh Valley Genomics testing sites: - Longwood Gardens. - Coatesville Public Safety Training Center. 3. The TS provided the test reports on 09/16/2020 at 2:45 pm 4. A review of the reports on 09/16/2020 at 3:00 pm revealed, the test location and report date were not on the reports. 5. Confirmation ID #s of test reports reviewed: Positive: - 611243495 - 615898757 - 615274867 - 620202483 - 616074036 - 616602722 - 617675634 - 616968483 - 618282882 - 618471320 Negative: - 619089761 - 611925051 - 615210310 - 620167864 - 615803875 - 617821960 - 618875795 - 613530602 - 611821849 - 614626341 6. From 05/07/2020 to 06/02/2020 - 19,418 specimen were analyzed for RapCov rapid COVID-19 antibody tests. 7. A conversation with the TS on 09/17/2020 at 8:45 am, confirmed the findings above.
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 lack of documentation, review of laboratory procedures and the Laboratory Service agreement and interview with the Manager Partner (MP), the Laboratory Director (LD) failed to provide overall management and direction in accordance with 42CFR493.1445. Findings Include: 1. Failure to ensure that a quality control (QC) program was established and maintained for RapCov to assure the quality of laboratory services provided at Chester County. Refer to D6093. 2. Failure to ensure that the quality assessment (QA) programs were established and maintained. Refer to D6094. 3. Failure to ensure that testing personnel received the appropriate training for a high complexity test prior to Covid 19 patient testing. Refer to D6102.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 lack of quality control (QC) records, Laboratory Service agreement, and the laboratory RapCov rapid Covid-19 procedure and interview with the Managing partner, the Laboratory Director (LD) failed to ensure that a QC program was established, and maintained to ensure the quality of services provided for the RapCov Covid 19 testing on 30 of 30 days at the Chester County testing sites. Findings Include: 1. The Laboratory Service Agreement between Lehigh Valley Genomics and Chester County (page 11) stated, "During each testing day, laboratory shall provide: Quality control of the Point of Care Testing pursuant to laboratory's standard operating procedures (SOPs)". 2. On the day of survey 8/24/2020, review of the RapCov rapid Covid-19 procedure revealed the policy did not include QC procedures. 3. The laboratory performed 19,418 Covid-19 testing on RapCov rapid Covid-19 kit from May to June 2020 4. The Managing Partner interviewed on 8/24/2020 at 13:00 could not provide documentation of QC program established for the RapCov rapid Covid 19 testing.
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 lack of Quality Assurance (QA) documentation, QA policy section QM policy 001 reviewed, and interview with the Managing Partner (MP), the Laboratory Director (LD) failed to ensure a QA program, was established and maintained to ensure the quality of services provided by the laboratory. Findings include: 1. The QA policy section QM policy number 001 (page 4 of 9) states: "Quality control protocols are followed to ensure proper instrument accuracy and performance". 2. The QA policy section QM policy number 001 (page 5 of 9) states: "Laboratory manager reviews and monitors Quality Control periodically to ensure protocol compliance". 3. On the day of survey 8/24/2020, a review of laboratory records revealed, the laboratory did not document QA activities in the laboratory nor for offsite testing locations. The laboratory could not provide a QA record. 4. The laboratory performed 55,000 non waived tests in the last 1 year according to CMS-116 submitted by the laboratory. 5. The Managing Partner confirmed there were no QA record on 8/24 /2020 at 13:30.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on review of training records, the Laboratory Service Agreement and interview with the Managing Partner, the laboratory director (LD) failed to ensure that the 72 of 72 testing personnel (TP) who performed RapCov rapid Covid 19 High Complexity testing at Chester County testing sites received appropriate training and demonstrated that they could perform all testing reliably and report accurate results from May, 2020 to June, 2020 Findings included: 1. The Laboratory Service Agreement states: " Provide Chester County with training materials to enable County-provided laboratory testing personnel (CLT-Personnel) to obtain appropriate training to performed to Point of Care Test on behalf of the Laboratory" was signed by Managing Partner. 2. On the day of survey, the laboratory could not provide training records for 72 of 72 TP who performed RapCov rapid Covid 19 at Chester County offsite testing locations. 3. The Managing Partner interviewed 8/24/2020 at 13:30 provided Chester County Drive-thru testing site staff Orientation and Briefing May 2020, and General Healthcare Resources (GHR) training which is not specific to RapCov rapid COVID-19 laboratory testing. 4. 19,418 patients were tested from 5/7/2020 thru 6/2/2020.