

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2221096	(X3) Date Survey Completed 03/30/2022
Name of Provider or Supplier Brevitest Laboratories	Street Address, City, State 3900 Essex Lane, Suite 575, Houston, TX	
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 initial survey was performed on 3/30/2022. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory and patient test records from 2021 and 2022, laboratory policies, and confirmed in interview, the laboratory failed to establish specimen storage and preservation; conditions for specimen transportation; and acceptability and rejection for one of one test: SARS-CoV-2 IgG ELISA. Findings included: 1. Review of the laboratory policy Off-Site Sample Management (Document 01.114 v1) revealed no documentation of the temperature requirements for specimen storage and preservation; conditions for specimen transportation; and acceptability and rejection for the finger stick blood in sample diluent for the SARS-CoV-2 IgG ELISA test. 2. Random review of patient test records collected off site from January 2022 and February 2022 included the following five patients: Date</p>

	<p>Accession # 1/27/2022 UKWB-LLIG 1/27/2022 DZNG-MDWC 1/28/2022 PIBZ-RFXS 1/28/2022 YHSB-WOIK 1/28/2022 QRLH-CNJC 3. An interview with the laboratory manager on 3/30/2022 at 1410 hours in her office confirmed the above findings. She stated that the laboratory performed stability studies but that the temperature range were not documented on the policies that corresponded to the studies performed.</p>
<p>D5400</p>	<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: Based on review of laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems. Refer to D5445, D5447</p>
<p>D5445</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory quality control and patient test records from December 2021 to February 2022, and confirmed in interview, the laboratory failed to document a complete IQCP (INDIVIDUALIZED QUALITY CONTROL PLAN) to reduce the frequency of quality control testing to once daily for all eight test systems used for SARS-CoV-2 IgG ELISA testing. Findings included: 1. Review of the laboratory records available revealed the laboratory used the following eight sample processing units (SPU) for SARS-CoV-2 IgG ELISA patient testing: BT-A01-0000-0119 BT-A01-0000-0123 BT-A01-0000-0121 BT-A01-0000-0124 BT-A01-0000-0130 BT-A01-0000-0131 BT-A01-0000-0132 BT-A01-0000-0133 2. Random review of the laboratory patient test records revealed the laboratory performed patient testing for the following 13 dates. A random sampling of patients include the following 15 patients: 12/29/2021 IPEJ-INDU 12/21/2021 VDNS-FAYQ 12/17/2021 VSFE-BXPG 12/14/2021 LKMG-KGZR 12/8/2021 OVQZ-EZJB 1/28/2022 EFYV-ELZQ 1/26/2022 GXNQ-XCYC 1/18/2022 BKQT-QKQV 1/11/2022 QZKW-DTDY 1/04/2022 QZVD-SOCS 2/4/2022 TIIP-AJHD 2/25/2022 FCKG-HPJW AFIA-CLSV 2/19/2022 BRQF-URPU WXXX-QHDW 3. Review of the laboratory records from December</p>

2021 to February 2022 revealed quality control was performed once each day of SARS-CoV-2 IgG testing for only one of the eight SPUs used. 4. Review of the laboratory records available revealed no documentation of an IQCP to modify the frequency of SARS-CoV-2 IgG quality control testing once each day for only one of the eight test systems in use. No Risk Assessment, Quality Control Plan, nor a Quality Assessment plan was available for review. 5. An interview with the laboratory manager on 3/30/2022 at 1330 hours in her office confirmed the above findings. She was unaware each SPU was a test system; thus the laboratory only performed testing daily for only one SPU, not all SPUs used in patient testing.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory quality control and patient test records from December 2021 to February 2022, and confirmed in interview, the laboratory failed to document an external quality control of two different concentrations each day of SARS-CoV-2 IgG testing on seven of eight sample processing units used. Findings included: 1. Review of the laboratory records available revealed the laboratory used the following eight sample processing units (SPU) for SARS-CoV-2 IgG ELISA patient testing: BT-A01-0000-0119 BT-A01-0000-0123 BT-A01-0000-0121 BT-A01-0000-0124 BT-A01-0000-0130 BT-A01-0000-0131 BT-A01-0000-0132 BT-A01-0000-0133 2. Random review of the laboratory patient test records revealed the laboratory performed patient testing for the following 13 days. No record was available for review to determine which SPU was used to perform patient testing. A random sampling of patients include the following 15 patients: 12/29/2021 IPEJ-INDU 12/21/2021 VDNS-FAYQ 12/17/2021 VSFE-BXPG 12/14/2021 LKMG-KGZR 12/8/2021 OVQZ-EZJB 1/28/2022 EFYV-ELZQ 1/26/2022 GXNQ-XCYC 1/18/2022 BKQT-QKQV 1/11/2022 QZKW-DTDY 1/04/2022 QZVD-SOCS 2/4/2022 TIIP-AJHD 2/25/2022 FCKG-HPJW AFIA-CLSV 2/19/2022 BRQF-URPU WXXX-QHDW 3. Review of the laboratory records from December 2021 to February 2022 revealed quality control was performed once each day of SARS-CoV-2 IgG testing. No record was available for review to determine which SPU was used to perform quality control testing. 4. Review of the laboratory records available revealed no documentation of an IQCP to modify the frequency of SARS-CoV-2 IgG quality control testing once each day for only one of the eight test systems in use. Cross refer to D5445 5. An interview with the laboratory manager on 3/30/2022 at 1330 hours in her office confirmed the above findings. She stated that she just started to document the SPU unit number when performing daily quality control but did not document which SPU is used for patients.

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 a review of the laboratory's quality control records, facility procedures, record review and staff interview, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services (refer to D6086, D6093)

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on review of the laboratory and patient test records from 2021 and 2022, and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete establishment studies for eight of eight sample processing units used for SARS-CoV-19 IgG prior to patient testing. Findings included: 1. Review of laboratory records revealed the laboratory started patient testing for SARS-CoV-19 IgG testing in December 2021. 2. Review of the laboratory records available revealed the laboratory used the following eight sample processing units (SPU) for patient testing: BT-A01-0000-0119 BT-A01-0000-0123 BT-A01-0000-0121 BT-A01-0000-0124 BT-A01-0000-0130 BT-A01-0000-0131 BT-A01-0000-0132 BT-A01-0000-0133 3. Review of the laboratory records available revealed no documentation of the establishment studies to include the above eight sample processing units used for patient testing. By not including all eight SPUs, the laboratory director cannot ensure the accuracy and reliability of each test system. 4. An interview with the laboratory manager on 3/30/2022 at 1420 hours in her office confirmed the above findings. She acknowledged that the establishment studies only included the three SPUs that are not currently being used for patient testing.

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 review of immunology quality control and patient test records and interview the laboratory director failed to ensure that quality control program were established to assure the quality of laboratory services provided. (refer to D5445, D5447)

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.

1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on a review of the Laboratory Personnel Report (CMS-209), personnel records and confirmed in interview, it was revealed that 1 of 2 testing personnel performing high complexity testing did not have the appropriate education credentials required to perform high complexity testing (refer to D6171).

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and

verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on a review of the CMS209, laboratory personnel files and confirmed in interview, it was revealed that the facility failed to have documentation that one of two testing personnel were qualified to perform high complexity immunology testing at the time of the survey. Findings were: 1. A review of facility personnel files revealed that one of two testing personnel failed to have educational documentation available for review at the time of the survey to qualify them to perform high complexity testing in Immunology. 2. An interview with the laboratory manager on 3/30/2022 at 1320 hours in the office confirmed the above findings. key: CMS - Centers for Medicare and Medicaid Services