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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>49D0668056    | <b>(X3) Date Survey Completed</b><br>03/07/2023 |
| <b>Name of Provider or Supplier</b><br>Elisa/Act Biotechnologies, Llc  | <b>Street Address, City, State</b><br>44621 Guilford Dr #150, Ashburn, VA |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D0000</b>              | An announced CLIA recertification survey was conducted at ELISA ACT Biotechnologies on March 7, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows: D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems, and D6076 - 42 C.F.R. 493-1441 Condition: High Complexity Laboratory Director.   |
| <b>D5217</b>              | <p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b><br/>CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of the laboratory's policies and procedures, tour, review of accuracy verification records, lack of documentation, and interviews, the laboratory failed to perform test accuracy verification twice annually for the Clifford Materials Reactivity Testing (CMRT) method in calendar years 2021 and 2022 during the nineteen months reviewed (July 2021 to March 7, 2023). Findings include: 1. During a laboratory tour with the General Supervisor (GS) at approximately 10:30 AM on March 7, 2023, the surveyor observed the laboratory utilizing a Spectra Max M2 microplate reader. The surveyor inquired what test method utilized the plate reader. The GS stated Clifford Materials Reactivity Testing (CMRT) utilizes the Spectra Max M2. 2. Review of the laboratory's policies and procedures revealed an procedure, "SOP LP-12: Quality Control Protocols for Clifford Materials Reactivity Testing (CMRT)" signed by the Laboratory Director on May 5, 2021. The procedure stated "CMRT looks for the presence of antibodies in patient serum at or above a relevant threshold which have been formed against the chemical groups and families of compounds that can be released from restorative and reconstruction biomaterials." 3. Review of the laboratory's twice annual accuracy verification records revealed a lack</p> |

of documentation of the CMRT method's accuracy verification for 2021 and 2022. The inspector requested to review documentation of the twice annual accuracy verification for the CMRT method for calendar years 2021 and 2022. The laboratory provided no documentation for review. 4. In an exit interview with the laboratory director, laboratory operations manager and general supervisor on March 7, 2023 at approximately 12:15 PM, the findings were confirmed.

**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 a tour, review of the laboratory's policies and procedures, method validation records, maintenance records, patient records, lack of documentation and interviews, the laboratory failed to: 1. validate the performance specifications of a laboratory developed test (LDT), Clifford Materials Reactivity Testing, prior to reporting nine-hundred fifty-two patient results from May 20, 2021 until the date of the survey on March 7, 2023 (see D5423); 2. establish the calibration and control procedure of a laboratory developed test (LDT), Clifford Materials Reactivity Testing, prior to reporting nine-hundred fifty-two patient results from May 20, 2021 until the date of the survey on March 7, 2023 (see D5425); 3. perform maintenance procedures as defined by the manufacturer for the SpectraMax M2 Multi-mode microplate reader from May 20, 2021 until the date of the the survey on March 7, 2023 (see D5429); and 4. document annual calibration checks for the SPECTRAtest Instrument Validation plate during the twenty-one (21) months reviewed from June 2021 until March 7, 2023 (see D5433).

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on a tour, review of the laboratory's policy and procedure manual, Food and Drug Administration's (FDA's) CLIA test categorization database, validation records, patient records and interviews, the laboratory failed to validate the performance

specifications of a laboratory developed test (LDT), Clifford Materials Reactivity Testing, prior to reporting nine-hundred fifty-two (952) patient results from May 20, 2021 until the date of the survey on March 7, 2023. The findings include: 1. During a tour of the laboratory on March 7, 2023 at approximately 9:30 AM, the surveyor noted the laboratory utilizes a SpectraMax M2 Multi-mode microplate reader. The surveyor inquired what testing utilizes the SpectraMax M2. The General Supervisor (GS) stated the SpectraMax is utilized when performing Clifford Materials Reactivity Testing. They stated the laboratory began testing in May 2021. 2. Review of the laboratory's policy and procedure manual revealed "SOP LP-12: Quality Control Protocols for Clifford Materials Reactivity Testing (CMRT)" signed/dated by the laboratory director (LD) on May 5, 2021. The protocol stated, "It is important to note that the specifications of the preparation of the reagents were created by Clifford Consulting & Research, Inc CLIA 06D0669295, and the rights were transferred to ELISA Act Biotechnologies on 12/10/2020." 3. Review of the FDA's database revealed no listing or categorization for Clifford Materials Reactivity Testing. During an interview with the GS on March 7, 2023 at approximately 10:45 AM, the GS revealed CMRT was a laboratory developed test (LDT) purchased from Clifford Consulting & Research on 12/21/2020. 4. The surveyor requested to review the validation of the performance specifications of the CMRT test. The laboratory provided a document titled "Validation for Clifford Materials Reactivity Testing CMRT" signed and dated by the LD on 5/1/2021. Review of the validation document revealed a lack of documentation of the accuracy, precision, analytical sensitivity, analytical specificity including substances, and reportable range for the CMRT. The surveyor requested to review the accuracy, precision, analytical sensitivity, analytical specificity including substances, and reportable range. The laboratory provided no documentation to review. 5. Review of patient records from May 21, 2021 until the date of the survey on March 7, 2023 revealed 952 patients were analyzed using CMRT. 6. In an exit interview with the laboratory director, laboratory operations manager and general supervisor on March 7, 2023 at approximately 12:15 PM, the findings were confirmed.

**D5425**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(3)

The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:  
Based on a tour, review of the laboratory's policy and procedure manual, Food and Drug Administration's (FDA's) CLIA test categorization database, validation records, patient records and interviews, the laboratory failed to establish and perform the calibration and control procedures for a laboratory developed test (LDT), Clifford Materials Reactivity Testing, prior to reporting nine-hundred fifty-two (952) patient results from May 20, 2021 until the date of the survey on March 7, 2023. The findings include: 1. During a tour of the laboratory on March 7, 2023 at approximately 9:30 AM, the surveyor noted the laboratory utilizes a SpectraMax M2 Multi-mode microplate reader. The surveyor inquired what testing utilizes the SpectraMax M2. The General Supervisor (GS) stated the SpectraMax is utilized when performing Clifford Materials Reactivity Testing. They stated the laboratory began testing in May 2021. 2. Review of the laboratory's policy and procedure manual revealed "SOP LP-12: Quality Control Protocols for Clifford Materials Reactivity Testing (CMRT)"

signed/dated by the laboratory director (LD) on May 5, 2021. The protocol stated, "It is important to note that the specifications of the preparation of the reagents were created by Clifford Consulting & Research, Inc CLIA 06D0669295, and the rights were transferred to ELISA Act Biotechnologies on 12/10/2020." 3. Review of the FDA's database revealed no listing or categorization for Clifford Materials Reactivity Testing. During an interview with the GS on March 7, 2023 at approximately 10:45 AM, the GS revealed CMRT was a laboratory developed test (LDT) purchased from Clifford Consulting & Research on 12/21/2020. 4. The surveyor requested to review the calibration and control procedures established for the CMRT test. The laboratory provided a document titled "Validation for Clifford Materials Reactivity Testing CMRT" signed and dated by the LD on 5/1/2021. Review of the validation document revealed a lack of documentation of the calibration and control procedures for CMRT. The surveyor requested to review the calibration and control procedures. The laboratory provided no documentation to review. 5. Review of patient records from May 21, 2021 until the date of the survey on March 7, 2023 revealed 952 patients were analyzed using CMRT. 6. In an exit interview with the laboratory director, laboratory operations manager and general supervisor on March 7, 2023 at approximately 12:15 PM, the findings were confirmed.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on a tour, review of the laboratory's policy and procedure manual, maintenance records, and interviews, the laboratory failed to perform maintenance procedures as defined by the manufacturer for the SpectraMax M2 Multi-mode microplate reader from May 20, 2021 until the date of the survey on March 7, 2023. The findings include: 1. During a tour of the laboratory on March 7, 2023 at approximately 9:30 AM, the surveyor noted the laboratory utilizes a SpectraMax M2 Multi-mode microplate reader. The surveyor inquired what testing utilizes the SpectraMax M2. The General Supervisor (GS) stated the SpectraMax is utilized when performing Clifford Materials Reactivity Testing. They stated the laboratory began testing in May 2021. 2. Review of the laboratory's policy and procedure manual revealed the SpectraMax M2 and M2e Microplate Reader User Guide. The user guide contained the following statements: "Chapter 6: Maintenance-Perform only the maintenance tasks described in this guide. Contact a Molecular Devices service engineer to inspect and perform preventative maintenance service on the instrument each year...Cleaning the Instrument-Periodically clean the outside surfaces of the instrument using a cloth or sponge that has been lightly dampened with water...Cleaning the Fan Filter-The fan filter on the bottom of the instrument requires periodic cleaning. The frequency of cleaning depends on the cleanliness of the lab and could range from once a month to once every six months." 3. Review of the laboratory's maintenance records revealed a lack of documentation of the annual preventive maintenance performed by the Molecular Devices service engineer, periodic cleaning of the instrument and fan filter from May 20, 2021 until the date of the survey on March 7, 2023. The surveyor requested to review the above listed maintenance documentation. The laboratory

provided no documentation to review. 4. In an exit interview with the laboratory director, laboratory operations manager and general supervisor on March 7, 2023 at approximately 12:15 PM, the findings were confirmed.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on a tour, manufacturer's user's manual, equipment calibration records, and an interviews, the laboratory failed to document annual calibration checks for one (1) of 1 SPECTRAtest Instrument Validation Plate utilized to qualify system performance of the SpectraMax M2 multi-mode microplate reader during the twenty-one months reviewed (June 2021 until March 7, 2023). Findings include: 1. During a tour of the laboratory on March 7, 2023 at approximately 9:30 AM, the surveyor noted the laboratory utilizes a SpectraMax M2 Multi-mode microplate reader. The surveyor inquired what testing utilizes the SpectraMax M2. The General Supervisor (GS) stated the SpectraMax is utilized when performing Clifford Materials Reactivity Testing. They stated the laboratory began testing in May 2021. The surveyor inquired how often they calibrate the reader. The GS stated they calibrate the reader monthly using the SPECTRAtest Validation Plate. The surveyor noted a SPECTRAtest Validation plate (serial #4237). 2. Review of the SPECTRAtest User's Manual for the SPECTRAtest Validation Plate, revealed the following manufacturer's instructions for calibration frequency: "...Molecular Devices recommends having SPECTRAtest Validation Plate be recertified yearly. Each SPECTRAtest Validation Plate returned to Molecular Devices for recertification is disassembled, cleaned, calibrated and returned with a new certificate of Calibration." 3. Review of the laboratory's equipment calibration records from June 2021 until March 7, 2023 revealed a Certificate of Calibration for the SPECTRAtest Instrument Validation Plate (Serial # 4237) with a Validation Calibration Date of June 2004 and Recalibration Date of July 2005. The surveyor requested to review documentation of the annual calibration checks for 2021 and 2022. The laboratory provided no records to review. 4. In an exit interview with the laboratory director, laboratory operations manager and general supervisor on March 7, 2023 at approximately 12:15 PM, the findings were confirmed.

**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 tour of the lab, review of the laboratory's policies and procedures, method

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|                     | <p>validation records, patient records, lack of documentation, and interviews the laboratory director failed to ensure: 1. the performance specifications for the laboratory developed test (LDT) Clifford Materials Reactivity Testing (CMRT) was validated prior to reporting nine-hundred fifty-two (952) patient results from May 20, 2021 until the date of the survey on March 7, 2023 (see D6086). 2. calibration and control procedures for the laboratory developed test (LDT) Clifford Materials Reactivity Testing (CMRT) were established and performed prior to reporting nine-hundred fifty-two (952) patient results from May 20, 2021 until the date of the survey on March 7, 2023 (see D6093).</p>  |
| <p><b>D6086</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a tour of the lab, review of the laboratory's policies and procedures, method validation records, patient records, lack of documentation, and interviews, the laboratory director failed to ensure the performance specifications for the laboratory developed test (LDT) Clifford Materials Reactivity Testing (CMRT) was validated prior to reporting nine-hundred fifty-two (952) patient results from May 20, 2021 until the date of the survey on March 7, 2023 (Cross Reference D5423).</p>  |
| <p><b>D6093</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a tour of the lab, review of the laboratory's policies and procedures, method validation records, patient records, lack of documentation, and interviews, the laboratory director failed to ensure calibration and control procedures for the laboratory developed test (LDT) Clifford Materials Reactivity Testing (CMRT) were established and performed prior to reporting nine-hundred fifty-two (952) patient results from May 20, 2021 until the date of the survey on March 7, 2023 (Cross Reference D5425).</p> |
| <p><b>D6128</b></p> | <p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b><br/>CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p>   |

This STANDARD is not met as evidenced by:

Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), initial performance specification records, testing personnel (TP) records, lack of documentation, and interview, the technical supervisor failed to provide documentation of the training and evaluation of training of four of four TP for the new Clifford Materials Reactivity Testing (CMRT) method prior to patient testing on May 20, 2021. Findings include: 1. Review of the CLIA CMS-209 Form revealed four TP performing patient testing. 2. Review of the initial performance specifications records for the new Clifford Materials Reactivity Testing method revealed patient testing utilizing the new CMRT method began on May 21, 2021. 3. Review of four TP records revealed a lack of documentation of training and evaluation of training for the new CMRT method prior to patient testing on May 21, 2021. The surveyor requested documentation of the training and evaluation of the 4 TP. The laboratory provided no documentation for review. 4. In an exit interview with the laboratory director, laboratory operations manager and general supervisor on March 7, 2023 at approximately 12:15 PM, the findings were confirmed.