Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0669013	**(X3) Date Survey Completed** 01/28/2020
Name of Provider or Supplier Elsa Medical Clinic	**Street Address, City, State** 101 S Broadway, Elsa, 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	A recertification survey was performed on January 28, 2020. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions of the Cholestech LDX Multianalyte quality control reagents, and confirmed in interview of facility personnel, it was revealed the laboratory failed to follow the manufacturer's instructions to ensure expired supplies were not available for use. The findings were: 1. Surveyor observation made on January 28, 2020 at 09:15 hours during the initial tour of the facility found the following expired item located in the laboratory storeroom refrigerator: Cholestech LDX Multianalyte Controls Lot Number: 003452B Expiration Date: 2019-12-25 Quantity: 1 package 2. A review of the manufacturer's instructions for the Cholestech LDX Multianalyte Control (Rev. 04/11) under the section titled "Warning and Precautions" revealed: "Note: Do not use the Controls past the expiration date printed on the vial labels." 3. An interview with a testing person #1 (as listed on Form CMS 209) on 01/28/2020 at 09:30 hours in the

	laboratory revealed the laboratory did not removed the expired package. She stated they had another unopened package of controls. Key: CMS - Centers for Medicare and Medicaid Services
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing (PT) records for 2018 Hematology (events 1, 2, and 3) and 2019 Hematology (events 1, 2, and 3) and confirmed in interview of facility personnel, the laboratory failed to retain 2 of 6 attestation records for a minimum of 2 years. Findings were: 1. A review of the laboratory's AAFP proficiency testing records from 2018 Hematology (events 1, 2, and 3) and 2019 Hematology (events 1, 2, and 3) found the laboratory failed to provide documentation of retaining 2 of 6 attestation statements. The missing attestation statements were as follows: 2018 Hematology (event 1) 2018 Hematology (event 2) 2. An interview with the technical consultant on 01/28/2020 at 10:40 hours in the break room confirmed the above findings. Key: CMS- Center for Medicare and Medicaid Services
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, patient records and confirmed in interview of facility personnel, the laboratory failed to follow their policy for specimen labeling. Findings were: 1. Surveyor observation made in the laboratory on January 28, 2020 found 5 CBC specimens. One (1) of 5 specimens was labeled with only the patient's name and date of birth. Seq # Date 8940 01/28/2020 2. Review of the laboratory's policy titled, "Procedure for Specimen Labeling" states a specimen should be labeled with "Patient's full name, Patient's Date of Birth, Name of requesting doctor and the current date. After the specimen is logged in the laboratory logbook, the laboratory identification number is also written on the specimen." The laboratory failed to follow its own specimen labeling policy. 3. Review of patient results found the laboratory tested the improperly labeled sample as follows: Seq# Date/Time tested 8940 01/28/2020 11:37:55 WBC 6.5 HGB 12.2 HCT 36.5 RBC 4.3 PLT 258 4. An interview with the testing person #1 (listed on Form CMS 209) on 01 /28/2020 at 09:40 hours in the laboratory confirmed the above findings. She acknowledged the laboratory was not following their own policy for labeling specimens. Key: CBC - Complete Blood Count WBC - White blood count HCT - Hematocrit PLT - Platelet RBC - Red blood cell Seq - Sequence CMS - Centers for Medicare and Medicaid Services

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the manufacturer's instructions for the Medonic M Hematology analyzer, review of the laboratory's environmental records from January 1, 2018 to December 31, 2019, and staff interview, the laboratory failed to include a humidity range for the laboratory. The findings were: 1. A review of the laboratory's policy titled "Reagent Management" under section B "Humidity" it states, "Some test systems are adversely affected by humidity. Establish acceptable humidity ranges. Document Humidity daily, using a hygrometer. If humidity falls outside the acceptable range, utilize a humidifier or a dehumidifier to remedy the problem." 2. A review of the manufacturer's instructions for the Medonic M Series (2017 article no1504493) under the section titled "Operating Environment" revealed humidity range 10%- 90%. 3. A review of the laboratory environmenal records from January 1, 2018 to December 31, 2019, the laboratory failed to include a humidity range. 4. An interview with the testing person # 1 (as listed on Form CMS 209) on 01/28/2020 at 15:55 hours in the conference room- after her review of the records - confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services Seq - Sequence
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records from June 2019 through January 2020, manufacturer instructions, patient test records, and confirmed in interview, the laboratory failed to verify new lot numbers of CBC (complete blood count) quality control material prior to their initial use. Findings were: 1. Review of the laboratory QC records from June 2019 to January 2020 revealed no documentation of the laboratory verifying the following Boule quality control materials prior to use:

	Lot 21905 exp 09/20/2019 Lot 21908 exp 12/25/2019 Lot 21911 exp 03/20/2020 (current lot) 2. Review of Manufacturer instructions for Medonic M series Analyzer under "Quality Control" it states, "New lot numbers of QC materials should be overlapped with existing lot numbers at least once to ensure proper reactivity. Run the current lot number of QC materials. Run the new lot number of QC materials. Print out copies of all results and save with other QC documentation for a minimum of two years." 3. Random review of patient records from January 1, 2020 to January 31, 2020 revealed the following patients were tested when the laboratory's current lot number of quality control (lot 21911) had not been verified. Seq # Date tested 8776 01/15/20 16:53 8940 01/28/20 11:37 4. The laboratory failed to have a policy on how to perform quality control overlap studies as required by the manufacturer. 5. A review of CMS 116 signed by the laboratory director 01/28/2020, revealed the laboratory performed 12,834 hematology tests annually. 6. An interview with the testing person #1 (as listed on form CMS 209) on 01/28/2020 at 14:15 hours in the break room confirmed the above findings. She stated that she instructed the other testing person to verify the quality control 5 times prior to use. Key: Exp - expired CMS - Centers for Medicare and Medicaid Services
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and confirmed in interview, the laboratory's quality assurance plan failed identify and correct errors in its analytic system. Findings were: NOTE: Review of the laboratory's quality assurance plan states, "Our laboratory implements an ongoing plan of quality assurance to objectively evaluate the quality of services provided. It is the responsibility of the laboratory director to oversee the successful implantation of the plan and to identify and correct problems as occur. Problems and their resolutions will be documented. The plan for quality assurance will be periodically reviewed to minimize the possibility of reoccurrence of identified problems. The plan will also be evaluated for overall quality of the laboratory services provided." 1. The laboratory failed to establish an acceptable humidity range for the laboratory environment. (refer to D5413) 2. The laboratory failed to perform lot to lot quality control studies prior to initial use. (refer to D5469) Key: TP - Testing person CMS - Center for Medicare and Medicaid
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on review of patient records and confirmed in interview with facility personnel, the laboratory failed to ensure 1 of 10 patient results were available in the patient's

	chart. The findings were: 1. Random review of 10 patient charts from January 2020, revealed the laboratory failed to ensure 1 of 10 CBC (complete blood count) final patient results were available in the patient chart. Seq # Date 8776 01/15/2020 2. Interview with testing personnel one (as listed on Form CMS-209) on 01/28/2020 at 15:00 hours in the laboratory confirmed the findings. She agreed the result was not available on the chart. Key: CMS - Centers for Medicare and Medicaid Services Seq - Sequence
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review laboratory of policy, review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing (PT) records from 2018 (events 1, 2, and 3) and 2019 (events 1, 2, and 3) and staff interview, it was revealed the laboratory director failed to ensure corrective actions were performed for proficiency testing failures. The findings were: 1. Review of the laboratory's policy titled, "Laboratory Director's Responsibilities," it states, "Ensure enrollment and successful participation in a proficiency testing program. Implement quality control and quality assurance systems. Implement remedial action systems." 2. A review of the laboratory's American Academy of Family Physicians proficiency testing records from 2019 Hematology (event A) revealed the laboratory had 3 failures for the non-regulated analyte, MCV (score 40%): HD-1 - fail HD-4 - fail HD-5 - fail 3. The laboratory was asked to provide documentation of corrective action for the failed analytes. No documentation was provided. 4. An interview with testing personnel #1 (as listed on Form CMS 209) on 01/28/2020 at 14:20 hours in the laboratory revealed the laboratory did not investigate or take corrective actions to correct the failures. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services. MCV - Mean corpuscular volume
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 the laboratory policy, laboratory's submitted Form CMS 209,

	review of laboratory personnel records, and staff interview, it was revealed the laboratory director failed to ensure that 1 of 9 testing personnel had documentation of required training prior to performing moderate complexity patient testing on the Medonic M hematology analyzer The findings were: 1. Review of the laboratory's policy titled, Laboratory Director's Responsibilities" signed by the Laboratory Director 1/13/16, it states, "Responsible for overall operation/administration of Lab. Employ competent personnel. Ensure accurate and reliable testing systems. May assume duties of Technical consultant/Supervisor, Clinical Consultant, and testing personnel. Implement quality control and quality assurance systems. Implement remedial action systems." 2. Review of the laboratory's submitted Form CMS 209 signed by the Laboratory Director 01/28/2020, revealed the laboratory identified 9 testing persons to perform moderate complexity testing. 3. Review of laboratory personnel records revealed testing person #6 (as listed on Form CMS-209) had an employee start date of 04/20/2019. According to the primary testing person, testing person #6 was still employed at the time of the survey, January 28, 2020, and was performing moderately complexity testing. 4. Further review of laboratory personnel records for testing person #6 revealed there was no documentation of training available for review prior to the testing person performing patient testing. 5. The laboratory was asked to provide documentation of training for testing person #6 (as listed on Form CMS-209) prior to patient testing. No documentation was provided. 6. An interview with testing person #1 (as listed on Form CMS-209) on 1/28/2020 09:45 hours in the break room confirmed the findings. Key CMS - Centers for Medicare and Medicaid Services
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of laboratory policy, review of laboratory personnel records, and confirmed in interview of facility personnel, the laboratory failed to: 1. Provide documentation of education records to ensure 1 of 9 testing persons were qualified to perform moderate complexity testing. (refer to D6065) 2. Provide documentation of training for 1 of 9 testing person in order to qualify them to perform moderate complexity testing (refer to D6066).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a

	high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of laboratory policy, laboratory records and confirmed in staff interview, it was revealed the laboratory failed to have documentation of education for 1 of 9 testing personnel to qualify them to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS-209 signed by the laboratory director on 1/28/2020 revealed the laboratory identified nine testing persons to perform moderate complexity testing. 2. Review of the laboratory's policy titled, "Laboratory Director's Responsibilities" signed by the laboratory director 01/13/2016, it states, "Responsible for overall operation/administration of Lab. Employ competent personnel..." 3. A review of the laboratory's personnel records for Testing Person #7 (as listed on Form CMS-209) revealed the testing person had a date if October 18, 2018. Further review of the testing person's records revealed no documentation of education records were available for review that would qualify them to perform moderate complexity testing. 4. An interview with the primary testing person on 01/28/2020 at 09:50 hours in the conference room revealed the laboratory did not have documentation of the education of the testing person. Testing person #7 was still employed by the facility and performing moderate complexity testing. Key CMS - Centers for Medicare and Medicaid Services
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the and training of 1 of 9 testing personnel to qualify them to perform moderate complexity testing. The findings were: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for 1 of 9 testing personnel. Testing Personnel # 6 (as listed on Form CMS-209) Employee start date: May 1, 2017 No initial training records 2. An interview with the technical consultant on 01/28/2020 at 09:50 hours in the conference room revealed the laboratory did not have documentation of initial training for the testing person. This confirmed the findings. She went on to say that the employee was still performing moderate complexity testing as of the date of the survey, January 28, 2020. Key: CMS - Centers for Medicare and Medicaid Services