Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0892806	09/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
City Of Laredo Health Department	2600 Cedar Ave, Laredo, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of a policy to address the competency assessment of general supervisors. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the facility identified 1 general supervisor. 2. A review of the laboratory's policies revealed the facility did not have documentation of a policy to address the competency assessment of general supervisors. 3. The laboratory was

	asked to provide documentation of a policy. No documentation was provided. 4. An interview with the general supervisor on 09/09/2021 at 1120 hours in the break room confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysists' (AAB) proficiency testing records from 2021, and staff interview, it was revealed the laboratory failed to have documentation reviewing results not evaluate or scored by the proficiency testing agency. The findings include: 1. A review of the laboratory's American Association of Bioanalysists' proficiency testing records from 2021 (Nonchemistry Q1 and Nonchemistry Q2) revealed the meaning of the following result flag: '?' - This score may not truly evaluate performance for the specimen which was not graded because of lack of consensus." 2. Further review of the proficiency testing records revealed the following results which were flagged with an 'f" and 'not graded' by the proficiency testing agency: a) Nonchemistry Q1 Gram Stain Morphology specimen 5 reported result: cocci intended: cocobacilli b) Nonchemistry Q2 Gram Stain specimen 7 reported result: gram positive intended: gram negative Gram Stain Morphology specimen 6 reported result: cocobacilli intended: Rods (bacilli) 3. The laboratory was asked to provide documentation of evaluating these results returned as not graded. No documentation was provided. 4. An interview with the general supervisor on 09/09/2021 at 1115 hours in the break room - after his review of the records- confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of following its procedure for assessing the pupating accuracy of testing personnel performing COVID-19 testing. The findings include: 1. A review of the laboratory's procedure titled "COVID-19 Testing Procedure using TAQPATH COVID-19 Combo Kit" (January 27, 2021) under the section titled "Proficiency Testing" revealed: "In order to ensure that lab personnel are using correct pipetting techniques, an internal proficiency test has been created and will be administered every 3 months for existing personnel and will be administered every time a new lab person is hired. Each proficiency test will consist of lab personnel running the quality control samples, negative control (NTC) and positive control (PC), along with 27 known positive samples (labeled PS1-PS27) and 6 water samples (labeled water) as

	outlined in Appendix D." 2. A review of personnel records identified 5 testing personnel who performed COVID-19 testing since this procedure was approved revealed there were 5 testing personnel who performed COVID-19 testing. They were (as listed on Form CMS 209): Testing personnel 1 Testing personnel 2 hired:2/23 /2021 Testing personnel 6 hired: 11/9/2020 Testing personnel 7 hired: 08/17/2020 terminated: 08/27/2021 Testing personnel 8 hired: 03/27/2020 terminated: 06/18/2021 3. The laboratory was asked to provide documentation of performing the 'proficiency testing' as listed in its procedure. No documentation was provided. 4. An interview with the general supervisor on 09/09/2021 09/09/2021 at 1230 hours in the break room revealed this section of the procedure had never been performed. This confirmed the findings.
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 review of the Arlington Scientific Inc. (ASI) RPR Card Test for Syphilis package insert, review of laboratory's random quality control (QC), maintenance and test records for rapid plasma regain (RPR) from August 18th to August 27th of 2021 and interview with the staff it was determined the staff failed to document end of shift needle cleaning as required for five of five records reviewed. The findings were: 1. Review of the Arlington Scientific Inc. (ASI) RPR Card Test for Syphilis package insert revealed: "The needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift." 2. Review of the laboratory's QC and maintenance records for RPR testing for August 18th to August 27th of 2021 revealed the records did not include the documentation of needle cleaning for five of five records. Reviewed record dates were: 08/18/2021 08/19/2021 08/20/2021 08/26/2021 08/27/2021 3. Review of the laboratory's test records for rapid plasma regain (RPR) for August 18th to August 27th of 2021 revealed testing was performed as follows: 08 /18/2021 patient samples tested: 410263 410264 410265 410267 410268 410269 410270 410271 410273 410275 410276 410292 410293 410295 08/19/2021 patient samples tested: 410297 410298 410300 410302 410303 410304 410305 410306 410307 410308 410318 410340 410342 410346 410348 410355 410356 410357 08/20 /2021 patient samples tested: 410460 410363 410380 410389 410390 08/26/2021 patient samples tested: 410488 410504 410511 410514 410516 410517 410519 410523 410524 410531 410540 410543 410544 410545 76047 08/27/2021 patient samples tested: 410550 410552 410553 410554 410555 410557 410558 410569 410573 410574 410584 410589 410590 4. In an interview on 09/09/2021 at 1200 hours in the break room Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 09/09/2021) stated that the laboratory does perform the needle cleaning, but does not document it. This confirmed the findings.
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 new lot establishment studies for October of 2019 to August of 2021 for the Sysmex XS-Series hematology analyzer controls, review of the laboratory's Sysmex XS-Series instrument's Control Charts and interview with the staff it was determined the laboratory failed to establish and follow processes to verify new control results correlate with the established limits for 12 of 12 control lots received in the laboratory. The findings were: 1. Review of the laboratory's new lot establishment studies for October of 2019 to August of 2021 for the Sysmex XS-Series hematology analyzer controls revealed there was no documentation of verification of control results' correlation with established limits for the following control lots received/used in the laboratory: Lot 9267; Expiration date 2019-12-15 Lot 9323; Expiration date 2020-02-09 Lot 0014; Expiration date 2020-04-05 Lot 0070; Expiration date 2020-05-31 Lot 0126; Expiration date 2020-07-26 Lot 0238; Expiration date 2020-11-15 Lot 0294; Expiration date 2021-01-10 Lot 0350; Expiration date 2021-03-07 Lot 1040; Expiration date 2021-05-02 Lot 1096; Expiration date 2021-06-27 Lot 1152; Expiration date 2021-08-22 Lot 1208; Expiration date 2021-10-17 2. The laboratory was asked to provide documentation of verifying new lots of control material. No documentation was provided. 3. In an interview on 09/09/2021 at 1000 hours in the break room Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 09/09/2021) stated that the laboratory does not perform new lot establishment studies for hematology controls. This confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's BSL3 room temperature and humidity records from April 2020 to June 2021, and staff interview, it was revealed the facility failed to have documentation of performing corrective actions when values were documented outside the laboratory's established acceptable ranges. The findings include: 1. A review of the laboratory's BSL3 room temperature and humidity records from April 2020 to June 2021 revealed the laboratory established the following acceptable ranges: Temperature: 15 - 30C Humidity: 30 - 85% 2. Further review of the records revealed the following times/days when the documented value was outside the laboratory's acceptable range without documentation of corrective actions being performed: a) April 2020 date value 04/14 12.6C 04/15 14.3C 04/16 14.3C 04/29 14.4

	C b) May 2020 date value 05/06 14.8C c) June 2020 date value 06/17 86% d) October 2020 date value 10/05 81% 10/08 14.8C 10/27 14.3C 14.1C e) December 2020 date value 12/07 29% 28% 12/08 29% f) January 2021 date value 01/05 27% 01/07 29% 01 /13 28% 01/14 29% 29% 01/15 28% 01/28 29% g) February 2021 date value 02/01 27% 02/02 29% 02/16 27% 26% 02/17 29% 02/19 28% 27% h) March 2021 date value 03/17 28% 03/18 28% 03/19 14.8C 29% 03/23 29% i) April 2021 date value 04 /01 29% 04/07 82% 3. The laboratory was asked to provide documentation of performing corrective actions. No documentation was provided. 4. A interview with the general supervisor on 09/09/2021 at 1323 hours in the break room - after his review of the records- confirmed the findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) Plan, review of the QA reports for 2020 and 2021 and interview with the staff it was determined the Laboratory Director failed to ensure QA Plan specific procedures are performed as per policy. The findings were: 1. Review of the laboratory's Quality Assurance (QA) Plan revealed "Specific procedures are as follow and will be performed a minimum of twice a year and documented." 2. Review of the laboratory's QA reports for 2020 and 2021 revealed the laboratory did not document twice a year the specific procedures defined in the laboratory's Quality Assurance policy. 3. In an interview on 09/09/2021 at 1000 hours in the break room Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 09/09/2021) stated that the laboratory does not follow the twice a year documentation of quality assurance processes. This confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing an annual competency on 1 of 2 testing personnel who required it. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed that 2 of the 3 testing personnel required annual competency assessment be performed in 2020. Testing personnel number 4 (as

	listed on Form CMS 209) did not have documentation of a competency assessment being performed in 2020. 3. The laboratory was asked to provide documentation of the missing competency assessment. No documentation was provided. 4. An interview with the general supervisor on 09/09/2021 at 1120 hours in the break room - after his review of the records- confirmed the findings.
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 review of the laboratory's Quality Assurance (QA) Plan, review of the QA reports for 2020 and 2021 and interview with the staff it was determined the Laboratory Director failed to ensure QA Plan specific procedures are performed as per policy. The findings were: 1. Review of the laboratory's Quality Assurance (QA) Plan revealed "Specific procedures are as follow and will be performed a minimum of twice a year and documented." 2. Review of the laboratory's QA reports for 2020 and 2021 revealed the laboratory did not document twice a year the specific procedures defined in the laboratory's Quality Assurance policy. 3. In an interview on 09/09/2021 at 1000 hours in the break room Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 09/09/2021) stated that the laboratory does not follow the twice a year documentation of quality assurance processes. This confirmed the findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical supervisor performing competency assessments semiannually within the first year of employment for 2 of 2 testing personnel who required it. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 5 personnel who performed high complexity testing. 2. A review of the laboratory's personnel records revealed that 2 of the 5 testing personnel required semiannual competency assessments be performed. They were (as listed on Form CMS 209): Testing personnel number 7 employed: 8/2020 to 8/2021 no competency assessments performed Testing personnel number 8 employed: 3/2020 to 6/2021 1 competency assessment performed 4/2020 3. The laboratory was asked to provide documentation of the missing competency assessments. No documentation was provided. 4. An interview with the general supervisor on 09/09/2021 at 1120 hours in the break room - after his review of the records- confirmed the findings.