Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0892806	07/17/2019
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
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: Review of the CMS 209 Laboratory Personnel Report, personnel records and confirmed in interview, the laboratory's competency assessment policy failed to include a procedure to evaluate the competency of all supervisors and consultants performing moderate complexity. The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report found that the laboratory designated two technical consultants for moderate complexity testing. 2. Review of personnel files found no documentation of competency assessment for technical consultant two (as listed on Form CMS-209). 3. Interview of technical consultant one (as listed on Form CMS-209) on July 17, 2019 at 10:15 hours confirmed that the laboratory director had not evaluated the competency of all supervisors and consultants. Key: CMS - Centers for Medicare and Medicaid Services
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:

	A. Based on review of laboratory polices, review of patient records, and confirmed in staff interview, it was revealed that the laboratory failed to follow its own policy for documenting Gram Stain quality control. The findings were: 1. Review of the laboratory's policy titled, "Standard Operating Procedure: Gram Stain" reviewed and approved by the technical director on March 10, 2019 under "Quality Control" it stated, "Quality control slides are available and should be done at least once per day that the procedure is performed or whenever a new lot of stain is opened. Results should be documented in the appropriate QC manual and signed by the Tech performing the test. QC slide contain both Gram Positive Cocci and Gram Negative Bacilli in different areas of the slide." 2. Interview with testing personnel three (as listed on Form CMS-209) on July 17, 2019 at 16:00 hours in the laboratory revealed that the laboratory's practice is to perform a patient Gram Stain if the colony count is greater than 100,000 for females and greater than 10,000 for males. 3. Review of Gram Stain quality control records from January 2019 to July 2019 found the following female patient records when the colony count was greater than 100,000 and the laboratory failed to follow its own policy to document quality control test performance based on patient culture colony counts: 387699 58494 385207 384413 383288 382611 382130 381834 380966 4. The laboratory failed to follow its own policy for Gram Stain quality control documentation. Key: QC - quality control CMS - Centers for Medicare and Medicaid Services B. Based on review of laboratory policy, manufacturer's instructions, review of patient records, and confirmed in interview the laboratory failed to follow its own written policy for sending platelet flagged results to a reference laboratory for 1 of 1 patients in 2019 (random review June-July 2019). Findings: 1. Review of CBC Confirmation policy page 5 stated: "6) Giant platelet/Platelet Clumps These may be counted as WBC's and may show in the histogram. If this is the case send the specimen out to the reference laboratory for correct count and pathology review." 2. Review of the Sysmex operator's manual revealed the following: "Suspect, PLT Clumps? The PLT Clumps? IP Message is determined by abnormal clustering if the DIFF scattergrams. Asterisks (*) will appear next to the PLT result. Dashes may appear in place of data for the MVP or the MPV may be marked with an asterisk (*). The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting." 3. Review of patient records in 2019 (random review) revealed the following: Patient ID 28653 CBC test date 06/14/2019 at 09:41 WBC result: 6.49* [10*3/uL] PLT result: 144*[10*3/uL] On the bottom of the result was a platelet estimate calculation: "12/8 X100= 150,000" The CBC was repeated on 06/14/2019 at 09:44 WBC result: 6.49*[10*3/uL] PLT result: 157*[10*3/uL] On the bottom of the result was a had written note stating: "platelet clumps" and a label stating: "VERIFIED BY REPEAT ANALYSIS AND BLOOD SMEAR" The laboratory failed to follow its own written policy and send the specimen to the reference laboratory for correct count and pathology review. 4. During an interview on 07/17 /2019 at 3:03 pm, testing person 1 (as documented on the CMS 209 form) stated that platelet clumps seen on a blood smear are sent out to the reference laboratory. 5. During an interview on 07/17/2019 at 3:30 pm, the laboratory director stated the patient's specimen was not sent to the reference laboratory, confirming the laboratory failed to follow its own written policy for sending platelet flagged results to a reference laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of laboratory's procedure manual, manufacturer's instructions, and confirmed in interview, the laboratory failed to implement a policy for establishing or defining QC ranges for acceptability for blood smears. Findings included: 1. The laboratory's procedure manual did not include procedures for establishing or defining QC ranges for acceptability for blood smears. 2. Review of Wright's Dip Stat Kit manufacturer's instructions revealed: "Procedure ... Note ...Nuclei stain blue. Neutrophilic granules are light blue while mast cell granules stain deep blue. Eosinophilic granules take up the eosin and stain red to pink. The cytoplasm of mature monocytes stains blue while neutrophil cytoplasm stains pink. Platelets stain various shades of blue/purple." 3. The laboratory began performing blood smears in December 2017. The annual manual CBC differential test volume was 1,416. 4. During an interview on 07/17/2019 at 11:16 am, the Laboratory Director stated the laboratory did not have a policy for establishing or defining QC ranges for acceptability for blood smears, confirming the above findings. II. Based on review of laboratory's procedure manual, manufacturer's instructions, and confirmed in interview, the laboratory failed to implement a policy for establishing or defining acceptability criteria for the comparison of manual differentials versus auto differentials for complete blood count (CBC) tests. Findings: 1. The laboratory's procedure manual did not include procedures for establishing or defining acceptability criteria for the comparison of manual differentials versus auto differentials for complete blood count (CBC) tests. 2. The laboratory began performing blood smears in December 2017. The annual manual CBC differential test volume was 1,416. 3. During an interview on 07/17/2019 at 2:11 pm, the Laboratory Director stated the laboratory did not have a policy for establishing or defining acceptability criteria for the comparison of manual differentials versus auto differentials for complete blood count (CBC) tests, confirming the above findings.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review laboratory policy, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for ensuring the correct procedure for Gram stains, The findings included: 1. Review of the manufacturer's instructions for HealthLink Gram Stain Set (Item number 400310, 400330, 400340, and 400342) stated the following: "Flood the prepared slide with Crystal Violet Stain for one minute and allow to stand for one minute. Rinse the slide gently with DI water. Flood the slide with Gram Iodine Working Solution and allow to stand for one minute. (When using Stabilized Iodine, flood the smear and allow to stand for approximately two minutes). Rinse slide gently with DI water. Rinse the slide gently with Decolorizer Solution for approximately 10 seconds or until or until the decolorizer runs clear from the slide. Rinse the slide gently with DI water. Flood the slide with Safranin stain and allow to stand for one minute. Rinse the slide gently with DI water and blot the slide dry with absorbent paper. Examine the slide accordingly." 2. Review of the laboratory's policy titled, "Standard Operating Procedure: Gram Stain" under "Procedure" it stated: "The procedure used in this laboratory is the Hucker's modification which is widely used for routine work: 1. Flood the fixed smear with Crystal Violet solution. Allow the stain to remain for approximately 30 seconds, 2. Decant the Crystal Violet, and rinse slide with running tap water. Caution: Excessive rinsing in this step could cause Crystal Violet to be washed out of Gram-positive cells. 3. Rinse off excess water with iodine solution, and then flood the slide with fresh iodine solution. Allow iodine to remain for approximately 30 seconds. 4. Decolorize by letting the reagent flow over the smear while the slide is being held at an angle. Stop when the runoff becomes clear. Adjust decolorization time according the thickness of the smear. 5 Remove excess decolorizer with gentle flow of tap water. Caution: Excessive rinsing this step could cause dye iodine complex to be washed from gram-positive cells. 6. Flood the slide with Safranin, and allow to counterstain for approximately 30 seconds. 7. Remove excess counterstain with a gentle flow of tap water. 8. Drain slide, and air dry. 9. Examine the smear microscopically." 3. The laboratory failed to ensure its policy reflected the manufacturer's instructions. 4. Interview with technical consultant one (as listed on Form CMS-209) on July 17, 2019 at 14:15 hours in the break room confirmed the findings. Key: DI - deionized 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, temperature/humidity charts, and confirmed in interview, the laboratory failed to ensure a humidity range was within range for the operation of Sysmex XS -1000i analyzer for 10 of 80 documented days in 2019 (random sampling from 01/2019 to 03/2019). Findings: 1. Review of the laboratory's

	"Standard Operating Procedure: CBC", page 3 revealed the following: "EQUIPMENT AND REAGENTS ... Equipment performance parameters: Operate within an ambient temperature range of 15-30C and relative humidity between 30-85%." 2. Review of laboratory temperature/humidity charts revealed the following days were not within range of 30-85% humidity to meet the requirements of the Sysmex XS -1000i analyzer's humidity for operation in 2019: 01/04/2019: 27.1% 01/23/2019: 22.9% 01 /29/2019: 22.2% 01/31/2019: 22.2% 02/08/2019: 22 % 02/25/2019: 26.2% 03/04 /2019: 24.7% 03/05/2019: 22.9% 03/06/2019: 21.8% 03/15/2019: 27.4% 3. During an interview on 07/17/2019 at 5:06 pm, the laboratory director confirmed the laboratory failed to ensure a humidity range was within range for the operation of Sysmex XS -1000i analyzer for the above-mentioned dates.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of quality control documentation, patient records, and interview with facility personnel, the laboratory failed to perform a titered positive (reactive) quality control on the ASI RPR Card Test for Syphilis. The findings included: 1. Review of the laboratory's policy titled, "ASI RPR Card Test for Syphilis" under, "Quality Control" it stated, "Controls with graded reactivity should be included daily to confirm optimal reactivity of the antigen ..." 2. Review of the manufacturer's instructions for the ASI RPR Card Test for Syphilis (Document No. 6004-900, 11-2016) under, "Quality Control" it stated, "Quality Control requirements must be performed in accordance with applicable local, state, and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls with graded reactivity should be included ..." 3. Random review of patient records from September 2018 to July 2019 revealed the following patient results were resulted semi-quantitatively when a positive quality control titer was not performed: Date: 09/27 /2018 Specimen ID: 377706 Patient Titer: 1:1 Date: 12/04/2018 Specimen ID: 380562 Patient Titer: 1:1 Date: 12/04/2018 Specimen ID: 380546 Patient Titer: >1:16 Date: 12 /11/2018 Specimen ID: 380337 Patient Titer: 1:2 Date: 03/27/2019 Specimen ID: 384017 Patient Titer: 1:2 Date: 05/28/2019 Specimen ID: 386036 Patient Titer: 1:16 Date: 05/28/2019 Specimen ID: 386017 Patient Titer: 1:1 Date: 07/03/2019 Specimen ID: 387302 Patient Titer: 1:8 4. Interview with testing personnel two, three, and four (as listed on Form CMS 209) on July 17, 2019 at 16:20 hours in the laboratory confirmed that patient titers were performed but quality control titers are not. Key: CMS - Centers for Medicare and Medicaid Services
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials

	for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, manufacturer's instructions, and confirmed in interview, the laboratory failed to test and document for intended reactivity (QC - quality control) of Wright's Dip Stat Kit stain for CBC (complete blood count) differentials in 2017, 2018 and 2019. Findings: 1. Review of Wright's Dip Stat Kit manufacturer's instructions revealed: "Procedure ... Note ...Nuclei stain blue. Neutrophilic granules are light blue while mast cell granules stain deep blue. Eosinophilic granules take up the eosin and stain red to pink. The cytoplasm of mature monocytes stains blue while neutrophil cytoplasm stains pink. Platelets stain various shades of blue/purple." 2. Review of QC records did not include for each day of use, documentation of the intended reactivity for the stain set for CBC differentials in December 2017, 2018, and 2019. The laboratory had an annual test volume of 1,416 manual CBC differentials. 3. During an interview on 07/17/2019 at 11:16 am, the Laboratory Director confirmed intended reactivity/QC was not tested for the CBC differential stain set.
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 temperature/humidity charts, corrective action log, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the documented humidity was outside the laboratory's established acceptable ranges for the operation of Sysmex XS -1000i analyzer for 10 of 80 documented days in 2019 (random sampling from 01/2019 to 03 /2019). Findings: 1. A review of the laboratory's temperature/humidity charts from 01 /2019-03/2019 revealed the laboratory documented the following humidity which were outside the laboratory's acceptable range for the following dates: 01/04/2019: 27.1% 01/23/2019: 22.9% 01/29/2019: 22.2% 01/31/2019: 22.2% 02/08/2019: 22 % 02/25/2019: 26.2% 03/04/2019: 24.7% 03/05/2019: 22.9% 03/06/2019: 21.8% 03/15 /2019: 27.4% In the 'corrective action' section next to each documented humidity was the note "To Be Monitor Hourly". 2. The laboratory was asked to provide documentation of performing corrective actions for the humidity documented out of acceptable range. No documentation was provided. 3. During an interview on 07/17 /2019 at 5:06 pm, the laboratory director confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, manufacturer's instructions, temperature/humidity charts, corrective action logs, and patient records, the laboratory failed to ensure an effective QA (Quality Assessment) system was in place to monitor, assess, and correct problems identified in the laboratory. Findings 1. The laboratory failed to follow its own written policy for sending platelet flagged results to a reference laboratory for 1 of 1 patients in 2019 (random review June-July 2019). Refer to D5401. 2. The laboratory failed to implement a policy for establishing or defining QC ranges for acceptability for blood smears. Refer to D5403-I. 3. The laboratory failed to implement a policy for establishing or defining acceptability criteria for the comparison of manual differentials versus auto differentials for complete blood count (CBC) tests. Refer to D5403-II. 4. The laboratory failed to ensure a humidity range was within range for the operation of Sysmex XS -1000i analyzer for 10 of 80 documented days in 2019 (random sampling from 01/2019 to 03 /2019). Refer to D5413. 5. the laboratory failed to test and document for intended reactivity (QC - quality control) of Wright's Dip Stat Kit stain for CBC (complete blood count) differentials in 2017, 2018 and 2019. Refer to D5473. 6. The laboratory failed to have documentation of performing corrective actions when the documented humidity was outside the laboratory's established acceptable ranges for the operation of Sysmex XS -1000i analyzer for 10 of 80 documented days in 2019 (random sampling from 01/2019 to 03/2019). Refer to D5785.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the Form CMS-209, personnel records, and confirmed in interview, the Technical Consultant failed to ensure that testing persons competency assessments were evaluated for manual differentials for CBCs. The findings were: 1. A review of the facility's personnel files revealed no documentation of the competency evaluations that included performing manual differentials for 3 of 4 testing personnel for manual differentials for CBCs. TP #2 (hire date February 1988) TP #3 (hire date December 2009) TP #4 (hire date December 2017) 2. An interview with the technical consultant on July 17, 2019 at 17:20 hours in the breakroom confirmed the findings. Key: CBC - complete blood count CMS - Centers for Medicaid and Medicare Services
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by:

	Based on review of the Form CMS-209, personnel records, review of patient records, and confirmed in interview, the Technical Consultant failed to ensure that testing personnel competency assessments included review of worksheets proficiency testing, and quality control for 3 of 4 testing persons performing RPRs (Rapid Plasma Reagin). The findings were: 1. A review of the facility's personnel files revealed no documentation of the competency evaluations that included review of worksheets, titered quality control records, and proficiency testing results, for 3 of 4 testing personnel for RPR testing. TP #2 (hire date February 1988) TP #3 (hire date December 2009) TP #4 (hire date December 2017) 2. An interview with the technical consultant on July 17, 2019 at 16:45 hours in the breakroom confirmed the findings. Key: CMS - Centers for Medicaid and Medicare Services