

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0892806	<b>(X3) Date Survey Completed</b> 01/05/2023
<b>Name of Provider or Supplier</b> City Of Laredo Health Department	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
<b>D5441</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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's quality control records for microscopic urinalysis testing from January 2022 to December 2022, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control values over time for quantitative red blood cell counts and quantitative white blood cell counts for 12 of 12 months. The findings include: 1. A review of the laboratory's microscopic urinalysis quality control records from January 2022 to December 2022 revealed the laboratory performed daily quality control testing utilizing two levels for quantitative red blood cell counts and quantitative white blood cell counts. 2. The laboratory was asked to provide documentation of assessing the quality control values over time to</p>

monitor accuracy and precision of test performance. No documentation was provided. 3. An interview with the general supervisor on 01/04/2023 at 1620 hours in the break room confirmed the laboratory did not monitor the quality control results over time.

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual method comparisons between automated and manual differentials. The findings include: 1. A review of the laboratory's test menu revealed the facility performed automated differentials and manual differentials. 2. The laboratory was asked to provide documentation of performing method comparison studies in 2022. No documentation was provided. 3. An interview with the general supervisor on 01/04/2023 at 1200 hours in the break room revealed the laboratory did not perform method comparisons between automated and manual differentials. 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 temperature records from November 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the monitored temperature was outside the laboratory's defined acceptable range. The findings include: 1. A review of the laboratory's temperature records from November 2022 revealed the daily temperatures which were documented outside the laboratory's defined acceptable ranges: a) Refrigerator (acceptable range 2-8C) Date Temperature 11/1 -0.86C (min) 11/2 -0.95 C (min) 11/3 -1.25C (min) 11/4 -1.03C (min) 11/5 -1.06C (min) 11/6 -1.05C (min) 11/7 -0.99C (min) 11/8 -0.91C (min) 11/8 9.82C (max) 11/9 -0.91C (min) 11/10 0.79C (min) 11/11 -0.77C (min) 11/12 -0.6C (min) 11/13 -0.58C (min) 11/14 -0.75C (min) 11/15 -0.79C (min) 11/16 -0.76C (min) 11/17 -0.65C (min) 11/17 8.97C (max) 11/18 0.01C (min) 11/19 0.2C (min) 11/20 0.25C (min) 11/21 -0.07C (min) 11/21 10.85C (max) 11/22 -0.1C (min) 11/22 13.41C (max) 11/23 -0.1C (min) 11/24 0.21C (min) 11/25 0.27C (min) 11/26 0.13C (min) b) Scientific Freezer (acceptable range -10 to -30 C) 11/8 -1.95C (max) 11/15 -8.21C (max) 2. The laboratory was asked to provide documentation of performing corrective actions. No documentation was provided. 3. An interview with the general supervisor on 01/05/2023 at 1000 hours in the break room - after his review of the records- confirmed the findings. Key min - minimum max - maximum C - degrees Celsius

**D5813**

**TEST REPORT**

CFR(s): 493.1291(g)

The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, review of the laboratory's critical values log sheets from October 2022 to December 2022, review of patient test requisitions, and staff interview, it was revealed the laboratory failed to have documentation of the notification of panic values to the provider for 5 of 18 records reviewed. The findings include: 1. A review of the laboratory's policy titled "Life Threatening (Panic) Values" (revision date: April 18, 2015) under the section titled "Policy" revealed: "The laboratory, with the approval from the clinical laboratory director, has defined a list of life threatening or panic values which must be reported immediately to the caregiver documented in the patient's order." 2. A review of the laboratory's critical values log sheets from October 2022 to December 2022 identified 5 of 18 total patient results which were documented as the patient and not the provider being notified of the panic value (Please see patient alias list). 3. A review of the patient requisitions for each of the 5 identified patients revealed the laboratory was provided both phone numbers and fax numbers to contact the providers. 4. An interview with the general supervisor (as listed on Form CMS 209) on 01/04/2023 at 1505 hours in the break room revealed the laboratory would sometimes contact the patient rather than the provider of the panic values. This confirmed the findings.

**D6053**

**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 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 personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing semi-annual competency assessments within the first year of employment for 1 of 1 testing personnel who required them. The findings include: 1. A review of the laboratory's personnel records revealed testing personnel number 6 (as listed on Form CMS 209) started performing patient testing in November 2021. 2. Further review of the personnel records for testing personnel number 6 revealed a competency assessment was performed in February 2022. There was not documentation of a second competency assessment being performed by November 2022. 3. An interview with the technical consultant (as listed on Form CMS 209) on 01/04/2023 at 0945 hours in the break room revealed a second competency assessment had not been performed by November 2022. 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 personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing annual competency assessments 1 of 5 testing personnel in 2022. The findings include: 1. A review of the laboratory's personnel records revealed testing personnel number 1 (as listed on Form CMS 209) revealed an annual competency assessment was performed in September 2021. 2. Further review of the personnel records for testing personnel number 1 revealed a competency assessment was not performed in 2022. 3. An interview with the technical consultant (as listed on Form CMS 209) on 01/04/2023 at 0945 hours in the break room revealed a a competency assessment had not been performed in 2022. This confirmed the findings.