

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1052873	(X3) Date Survey Completed 02/06/2023
Name of Provider or Supplier Coastal Children's Clinic Pa	Street Address, City, State 5945 Saratoga Blvd, Corpus Christi, 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	Based on an announced validation survey performed on February 6, 2023, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6033 - 42 C.F.R. 493.1409 Condition: technical consultant
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to retain 1 of 3 attestation sheets for at least two years from January 2022 to December 2022. The findings included: 1. Review of the laboratory's policy titled, "Proficiency Testing" approved by the Laboratory Director on April 6, 2022, it stated, "C. Record Keeping: All Proficiency Testing records must be kept for a minimum of two years to include dates between CLIA survey cycles." 2. Review of the laboratory's API proficiency testing records from January 2022 through December 2022 found the laboratory failed to retain the attestation form for Hematology (event 1). 3. In an interview at 10:40 hours in the break room, the Laboratory Supervisor confirmed the laboratory did not have evidence of retaining the record. Key: CLIA - Clinical Laboratory Improvement Amendments</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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</p>

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 surveyor observation, review of manufacturer's instructions, laboratory temperature records, and confirmed in interview of laboratory personnel, the laboratory failed to define an acceptable room temperature range for 4 of 4 months reviewed from September 2022 to December 2022. The findings included: 1. Surveyor observation made on February 6, 2023 at 10:10 hours in the laboratory found the laboratory utilized a Sysmex XP-300 to perform moderate complexity testing for the specialty of Hematology. 2. Review of the manufacturer's instructions for the Sysmex XP-300 (operator's manual, revision February 2013) under 14.1 Specifications, stated, "Operating Environment: Ambient temperature: 15 to 30 degrees Celsius." Note: There was a post-it note on the page with the following handwritten note: "15-30 degrees Celsius 59-86 degrees Fahrenheit Equivalent" 3. Review of the laboratory's temperature records from September 2022 to December 2022 found the laboratory had a defined room temperature range of 50 - 77 degrees Fahrenheit. a. No temperatures were found documented outside of the instrument's operating range. 4. In an interview at 11:33 hours in the break room, the Laboratory Supervisor confirmed the findings.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of education to qualify 2 of 2 technical consultants from January 2022 to December 2022 (refer to D6035).

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the

technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of education to qualify 2 of 2 technical consultants from January 2022 to December 2022. The findings included: 1. A review of the laboratory's personnel records for 2 of 2 technical consultants in 2022 did not contain complete documentation to qualify them as technical consultants. Technical Consultant 1 (no longer employed as of December 2022) a. Transcript on file did not show a confirmed graduation date. b. The Bachelor of Science diploma on file did not contain the field of study. Technical Consultant 2 (the current Laboratory Supervisor) a. Employee does not have a minimum of a Bachelor of Science degree in a chemical, physical, biological, or clinical laboratory science degree. 2. In an interview at 11:00 hours in the break room, the Laboratory Supervisor confirmed the findings.