Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0931690	07/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Abc Pediatrics	3675 Boca Chica Blvd Suite E, Brownsville, 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
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) (c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood - non-automated (3) Ovulation tests visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. (d) Revisions to criteria for test categorization and the list of waived tests. HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Consult Strep A Test Dipsticks, the Consult COVID-19/Flu A&B Antigen Test, the Quidel QuickVue SARS Antigen Test, surveyor observation and staff interview, the laboratory failed to have documentation of monitoring the storage temperature for the identified waived test kits. The findings included: 1. Manufacturer's instructions for the Consult Strep A Test Dipsticks stated kits were required to be stored at 36 - 86F (2 - 30C). 2. Manufacturer's instructions for the Consult COVID-19/Flu A&B Antigen Test stated

	kits were required to be stored at 36 - 86F (2 - 30C). 3. Manufacturer's instructions for the Quidel QuickVue SARS Antigen Test stated kits were required to be stored at 59 - 86F (15 - 30C). 4. Surveyor observation on July 28, 2026 at 0915 hours in the store room identified the following kits: a) Consult Strep A Test Dipsticks 1 box of 50 tests b) Consult COVID-19/Flu A&B Antigen Tests 20 boxes of 25 tests each c) Quidel QuickVue SARS Antigen Test 10 boxes of 25 tests each 5. The laboratory did not have documentation of monitoring the temperature of the storage room. 6. The technical consultant confirmed the findings in an interview conducted on July 28, 2026 at 0925 hours in the storage room.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 blood collection devices contained in the storage room, and staff interview, the laboratory failed to have documentation of establishing and monitoring the temperature of the blood collection tubes. The findings included: 1. Surveyor observation on July 28, 2026 at 0915 hours in the store room identified the following blood collection devices: a) Blood collection devices 47,500 blood capillary tubes The collection devices were labeled as "K2 EDTA Blood Collection Tubes"and had a documented expiration date. The packaging did not contain manufacturer information or storage requirements. 2. The laboratory did not have documentation of establishing or monitoring the temperature of the storage room. 3. The technical consultant confirmed the findings in an interview conducted on July 28, 2026 at 0925 hours in the storage room.