Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503140	01/20/2020
Name of Provider or Supplier	**Street Address, City, State**	
South Padre Island Pediatric Center	3845 S Padre Island Dr, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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 to be 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: I. Based on direct observation, review of manufacturer's instructions, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions for monitoring revised expiration dates for glucometer test strips and quality control reagents. The findings were: 1. Direct observation made in the laboratory on January 20, 2020 at 08:45 hours found glucometer True Metrix Control Solution levels 2 and 3 (lot number 9BC2A37, expiration date: 04-30-2021) with an open date of 10-02-2019. 2. Direct observation made in the laboratory on January 20, 2020 at 08:45 hours found glucometer True Metrix test strips (lot number MV2945S, expiration date: 03-31-2020) with an open date of 05-14-2019. 3. Review of the

	manufacturer's instructions for True Metrix Control Solution (PVN C0118, R5SUN03 rev 41) under, "Storage and Handling" it stated, "Write the date first opened on bottle. Discard bottle after expiration date printed on the bottle label or 3 months after date written on bottle, whichever comes first. Discard any bottle that appears to be cracked or leaking." a. Quality control materials should have been discarded 01-02-2020. 4. Review of the manufacturer's instructions for True Metrix Pro Professional Monitoring Blood Glucose Test Strips (PVN C0118 R3SUNP03 rev 50) under "Caring for Strips" it stated, "Write date opened on test strip vial label when removing the first test strip. Discard all unused test strips in the vial after either date printed on the test strip vial label or 4 months after date opened, whichever comes first. Using test strips past these dates may cause inaccurate results. a. Test strips should have been discarded 09-14-2019 5. The laboratory failed to follow the manufacturer's instructions to monitor revised expiration dates per the manufacturer's instructions. 6. The findings were confirmed in interview with Testing Personnel 1 (as listed on Form CMS-209) on January 20, 2020 at 10:00 hours in the office. II. Based on review of manufacturer's instructions, review of patient records, and confirmed in interview of laboratory personnel and distributor, the laboratory failed to follow the manufacturer's instructions for acceptable patient use. The findings were: 1. Review of the manufacturer's instructions for the True Metrix Pro Professional Monitoring Blood Glucose System (RE4NPDP03, Rev 4) under, "Important Safety Information" it stated, "Do not use for the diagnosis or screening for diabetes mellitus or for the measuring of blood glucose in newborns." 2. Random review of patient records found the following patients were tested and did not have documentation of a diagnosis of diabetes mellitus: See Patient Alias List 3. Interview with the technical consultant on January 20, 2020 at 10:45 hours in the office confirmed the findings. 4. Interview with a representative of [manufacturer name redacted] on January 21, 2020 at 10:35 hours confirmed that the glucometer should only be used on patients with a diagnosis of diabetes. Key: CMS - Centers for Medicare and Medicaid Services
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records from 2018 and 2019 and confirmed in interview of laboratory personnel, the laboratory failed to provide documentation of the laboratory director signing 1 of 6 attestation statements reviewed. The findings were: Note: As of the date of the survey, the laboratory did not have documentation of a delegation of duties for the current technical consultant. 1. Review of API's 2018 (event 2) Attestation Statement, it stated, "Signatures Required - Testing personnel and the laboratory director must physically sign an attestation statement for all PT results, and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 2. Review of the laboratory's API proficiency testing records for hematology 2018 (events 1, 2, and 3) and 2019 (events 1, 2, and 3) revealed the laboratory failed to provide documentation of the laboratory director signing the following 1 of 6 attestation statements reviewed: 2018 (event 2): the area for the laboratory director's signature was signed by testing personnel 1 (as listed on Form CMS-209). 3.

	Interview with the technical consultant on January 20, 2020 at 09:26 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records from 2018 and 2019 and confirmed in interview of laboratory personnel, the laboratory failed to retain 2 of 6 attestation statements. The findings were: 1. Review of API's 2018 (event 2) Attestation Statement, it stated, "Signatures Required - Testing personnel and the laboratory director must physically sign an attestation statement for all PT results, and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 2. Review of the laboratory's API proficiency testing records for hematology 2018 (events 1, 2, and 3) and 2019 (events 1, 2, and 3) revealed the laboratory failed to provide documentation of retaining the following 2 of 6 attestation statements: 2018 (event 3) 2019 (event 1) 3. Interview with the technical consultant on January 20, 2020 at 09:26 hours in the laboratory confirmed the findings.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review patient results and confirmed in interview of laboratory personnel, the laboratory failed to provide documentation having a written or electronic request for patient testing for 1 of 10 patient records reviewed. The findings were: 1. Review of test records revealed the following 1 of 10 patient records reviewed did not have documentation of a written or electronic request: Report had patient 1st name only Date of Birth: month not legible-14-58 2. On January 20, 2020 at 10:45 hours, the laboratory was asked to provide the chart for review of records. No documentation was provided. Therefore, no written or electronic order for the CBC (Complete Blood Count) was available for review. 3. Interview with Testing Personnel 1 (as listed on

	Form CMS-209) on January 20, 2020 at 11:10 hours in the laboratory confirmed the findings. She revealed there was no chart because the test was performed on a provider. Key: CMS - Centers for Medicare and Medicaid Services
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of calibration verification records, and confirmed in interview of laboratory personnel, the laboratory failed to provide documentation of performing calibration verification every six months on the QBC Star hematology analyzer. The findings were: 1. Review of the manufacturer's instructions for the QBC Star hematology analyzer from Drucker Diagnostics stated, "Extended Range Controls: Drucker Diagnostics offers the Extended Range Control (ERC) kit for Calibration Verification. Calibration Verification must be tested once every six months or after a major repair or replacement of the instrument ..." 2. Review of the laboratory's calibration verification records from 2018 and 2019 revealed the laboratory failed to have documentation of performing the required calibration verification procedures every six months as required by the manufacturer. May 2018 July 2019 (14 months later) 3. Interview with testing personnel 1 (as listed on Form CMS-209) on January 20, 2020 at 10:42 hours in the office confirmed the findings. CMS - Centers for Medicare and Medicaid Services
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on review of patient records and confirmed in interview of facility personnel,

	the laboratory failed to provide documentation of 1 of 5 patient results maintained in the patient's chart. The findings were: 1. On January 20, 2020, the laboratory was asked to provide documentation of CBC results being maintained in the patient chart for 5 randomly selected patient CBC results. The following 1 of 5 patient results was not available in the patient's chart: Patient 1: Date of Birth 11-09-2000 Collection Date: 08-06-2019 Hematocrit: 44.7% Hemoglobin: 14.8 g/dL MCHC: 33.1 g/dL Total WBC: 12.5 X 10^9/L Granulocytes: 11.2 X 10^9/L % Granulocytes: 90 % Lymphs + Monos: 1.3 X 10^9/L % Lymphs + Monos: 10% Platelets: 407 X 10^9/L 2. Interview with testing personnel 1 (as listed on Form CMS-209) on January 20, 2020 at 10:33 hours in the office confirmed the findings. Key: CBC - complete blood count g - gram dL - deciliter MCHC - mean cell hemoglobin concentration Lymphs - lymphocytes Monos - Monocytes CMS - Centers for Medicare and Medicaid Services
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records from 2018 and 2019 and confirmed in interview of laboratory personnel, the laboratory director failed to ensure PT reports were reviewed. The findings were: Note: As of the date of the survey, the laboratory did not have documentation of a delegation of duties for the current technical consultant. Therefore, the laboratory director should review and evaluate proficiency testing reports. 1. Review of the laboratory's API proficiency testing records for hematology 2018 (events 1, 2, and 3) and 2019 (events 1, 2, and 3) revealed the laboratory director failed to review and evaluate the following 1 of 6 events reviewed: 2018 (event 1) 2. Interview with the technical consultant on January 20, 2020 at 09:26 hours in the laboratory confirmed the findings.