Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1037554	10/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Raymondville Pediatrics	640 S Expressway 77, Suite 2, Raymondville, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of patient reports, and confirmed in interview of facility personnel, the laboratory's policy for resolving abnormal CBC results did not reflect the laboratory's current practice. The findings were: 1. Review of the laboratory's policy titled, "Policy for Abnormal Differentials" approved by the laboratory director on July 24, 2013 stated, "If your CBC instrumentation is showing alarms (R1, R2, M#, etc.) in the differential section of the report, it will be considered an abnormal differential and Laboratory Director must be notified for further instruction." 2. The policy did not reflect how to the laboratory resolves flags on its current analyzer, the Sysmex. 3. Interview with testing personnel one (as listed on Form CMS 209) on October 19, 2018 at 10:30 hours in Room 5 confirmed the findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as

	acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of calibration records, and confirmed in interview of facility personnel, the laboratory failed to perform calibrations on the Sysmex every 6 months. The findings were: 1. Review of the laboratory's policy titled, "Calibration Validation" (no approval date) stated, "It is the policy of this lab to validate calibrations: every 6 months, following a complete reagent change, following major preventative maintenance, following replacement of a critical part or when shifts or trends in QC are seen." 2. Review of the laboratory's calibration records for 2017 and 2018 revealed calibrations were performed as follows: March 2, 2017 July 28, 2017 October 25, 2017 July 10, 2017 (9 months later) September 19, 2018 3. Interview with the technical consultant on 10/19/2018 at 11:00 hours in Room 5 confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the FDA and CLIA Complexity website, review of manufacturer's instructions, review of the laboratory's Individualized Quality Control Plan (IQCP) procedure, and interview with facility personnel, the laboratory failed to have a complete IQCP. The findings included: 1. Based on review of Food and Drug Administration (FDA) decision summary K162451, the analyte Streptococcus Group A & G is moderate complexity. 2. Review of the manufacturer's instructions for Quidel Molecular Strep A + G Control Set (PIM111000EN00 12/15) under, "Quality Control" it stated, " ...Each laboratory should establish their own Quality Control ranges and frequency of QC testing based on applicable local laws, regulations and standard good laboratory practice." 3. Review of the IQCP, signed by the laboratory director on March 20, 2017, revealed the laboratory failed to retain the data and documentation of quality control to support its plan to reduce quality control frequency to running a positive and negative external control per each lot and shipment and monthly thereafter. 4. Review of the risk assessment portion of the IQCP for the Quidel Solana Strep Molecular included potential sources of error and mitigation strategies. a. The Risk Assessment DID NOT include the frequency with which the laboratory defined potential sources of error had occurred or were likely to occur. b. As a potential risk, the laboratory identified "Patient and Specimen Identification." The laboratory failed to identify the frequency of improperly collected specimens for the Quidel Solana Strep Molecular test. 5. The Risk Assessment DID NOT include an assessment of the potential impact on patient results for each laboratory defined potential source of error. a. The lab defined "Training" as a

	potential risk of error. The laboratory did not define the potential impact on patient testing when testing personnel have not been trained in all aspects of the test method. 6. In an interview at 12:00 hours on 10/19/2018 in Room %, the Technical Consultant stated that the quality control study could not be found and agreed the frequency and impact of each source of error as part of the IQCP risk assessment was missing as part of the IQCP.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (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 Individualized Quality Control Plan (IQCP), review of quality control records, review of patient records, and confirmed in interview of facility personnel, the laboratory's quality assurance (QA) plan failed to identify and correct that the laboratory failed to follow its IQCP to perform external quality control testing monthly. The findings were: 1. Review of the laboratory's IQCP signed by the laboratory director on March 2, 2017, revealed the laboratory would perform external quality control with each new lot, shipment, and monthly. 2. Review of the laboratory's quality control records for July 2018, August 2018, September 2018, and October 2018 revealed the laboratory performed external quality control testing on the following dates: July (no records available for review) August (no records available for review) September 17, 2018 October 4, 2018 3. Review of laboratory PCR (polymerase chain reaction) logs revealed the laboratory tested 97 patients in July and 185 in August when quality control procedures had not be performed (see patient alias list). 4. Interview with testing personnel one (as listed on Form CMS 209) on 10/19/2018 at 12:30 hours confirmed the findings. She revealed that the quality control had been performed but they were still locating the records.