Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1032356	09/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
All Children's Pediatric Clinic, Pa	1313 S Closner Suite # A, Edinburg, 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	A recertification survey was conducted 09/10/2019. This facility was found NOT in compliance with the CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1250 Analytic systems
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: Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to monitor revised expiration dates for Kenlor Liquid H.pylori human IgG Antibody Serum Control. The findings were: 1. Surveyor observation on 09/10/19 at 0900 hours in the laboratory found the following expired item: 1 bottle of Kenlor Liquid H. Pylori Human IgG Antibody Serum Control Kit, Lot number: 50303 Expiration date: February 2021 Date opened 09/09/2019 The laboratory failed to label the reagent with the revised expiration date. 2. Review of the manufacturer's instructions for the Kenlor Liquid H. Pylori Human IgG Antibody Serum Control Kit (rev. 150303-056925) under, "Storage and Stability" it stated, "The product is stable up to the expiration date printed on the label if kept at 2- 8 C and 6 months at room temperature. Once opened it is stable for 60 days." 3. Interview with the technical consultant on 09/10/2019 at 09:30 hours in the laboratory confirmed the findings. Key: C- Celsius IgG- Immunoglobulin G H. - Helicobacter
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)

	The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and confirmed in interview of facility personnel, the laboratory failed to perform proficiency testing samples the same way as patient samples. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing" no approval date by the laboratory director, it stated, " ...PT specimens are to be treated the same as patient samples. The lab should document all steps taken in PT performance. All records and reports will be maintained for two years." 2. Review of the laboratory's policy titled, "Critical Values" approved by the laboratory director on August 10, 2015 stated, "The laboratory Personnel will repeat all CBC's outside the critical/panic value range ..." It went on to list the following ranges: WBC 2.0 - 22.0 cu.mm HGB 7.5 - 18 g/dL HCT 24 - 55 % PLT 50 - 800 cu. mm 3. Review of the laboratory's API proficiency testing records revealed the following PT samples were not handled the same way as patient samples. Each sample was tested twice even though, they did not match the laboratory's repeat criteria policy. 2017 Hematology (event 2) Sample ID: HSY-07 Run 1: 07/24/2017 @ 16:10 Run 2: 07/24/2017 @ 16:15 2018 Hematology (event 1) Sample ID: HSY-02 Run 1: 03/19/2018 @12:30 Run 2: 03/19/2018 @ 12:31 2018 Hematology (event 2) Sample ID: HSY-07 Run 1: 07/17/2018 @ 09:44 Run 2: 03/17/2018 @ 09:46 2018 Hematology (event 2) Sample ID: HSY-08 Run 1: 07/17/2018 @ 09:48 Run 2: 07/17 /2018 @ 09:50 2018 Hematology (event 2) Sample ID: HSY-09 Run 1: 07/17/2018 @ 09:52 Run 2: 07/17/2018 @ 09:53 2018 Hematology (event 2) Sample ID: HSY-10 Run 1: 07/17/2018 @ 09:55 Run 2: 07/17/2018 @ 09:56 2018 Hematology (event 3) Sample ID: HSY-12 Run 1: 11/14/2018 @ 15:36 Run 2: 11/14//2018 @ 15:37 2018 Hematology (event 3) Sample ID: HSY-13 Run 1: 11/14/2018 @15:39 Run 2: 11/14 /2018 @ 15:41 2018 Hematology (event 3) Sample ID: HSY-15 Run 1: 11/14/2018 @ 15:48 Run 2: 11/14/2018 @ 15:50 2019 Hematology (event 1) Sample ID: HSY-02 Run 1: 03/20/2019 @ 17:11 Run 2: /2019 @ 17:12 2019 Hematology (event 1) Sample ID: HSY-03 Run 1: 03/20/2019 @ 17:14 Run 2: 03/20/2019 @ 17:15 2019 Hematology (event 1) Sample ID: HSY-04 Run 1: 03/20/2019 @ not legible Run 2: /2019 @ not legible 2019 Hematology (event 1) Sample ID: HSY-05 Run 1: 03/20 /2019 @ not legible Run 2: 03/20/2029 @ not legible 2019 Hematology (event 2) Sample ID: HSY-07 Run 1: 07/23/2019 @ 16:14 Run 2: 07/23/2019 @ 16:15 2019 Hematology (event 2) Sample ID: HSY-09 Run 1: 07/23/2019 @ 16:19 Run 2: 07/23 /2019 @ 16:21 2019 Hematology (event 2) Sample ID: HSY-10 Run 1: 07/23/2019 @ 16:25 Run 2: 07/23/2019 @ 16:26 4. The findings were confirmed in interview with Testing Personnel #1 (as listed on Forms CMS-209) on September 10, 2019 at 10:28 hours when she revealed that the prior laboratory manager had instructed them to repeat the PT samples and compare them. Key: CBC - complete blood count WBC - white blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet cu.mm - cubic millimeter g/dL - grams per deciliter CMS - Centers for Medicare and Medicaid Services

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor observations, review of manufacturer's instructions, review of quality control records, patient records, and confirmed in interview of facility personnel, the laboratory failed to monitor the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to follow the manufacturer's instructions for proper cleaning and decontamination procedures for the Quidel Solana anlyzers (refer to D5411-A). 2. The laboratory failed to follow the manufacturer's instructions for proper pipetting technique when using a high performance micropipette (refer to D5411-B). 3. The laboratory failed to ensure verification studies were complete prior to testing patients when it implemented two Quidel Solana analyzers in October 2017 (refer to D5421). 4. The laboratory failed to perform external positive and negative quality control each day of patient testing for the Quidel Solana (refer to D5449).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: B. Based on surveyor observation, review of manufacturer's instructions, patient results, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for pipetting technique when using a VWR Signature Ergonomic High Performance Pipettor. The findings were: 1. Surveyor observation made on 09/10/2019 at 13:44 hours revealed Testing Personnel #2 (as listed on Form CMS-209) performing a patient run of Quidel Solana Streptococcus A and Quidel Solana Streptococcus C & G. It was observed that when using the blow-out micropipette after introducing 50uL of sample to the test well and mixing he would aspirate varied amounts of sample and discard the sample into the trash. 2. Review of the manufacturer's instructions for the VWR Signature Ergonomic High Performance Pipettor under, "Dispensing" it stated, "Press the push button to the second stop to expel any remaining liquid." 3. Review of the manufacturer's instructions for the Solana Strep Complete Assay (CLM305001EN00(11/16) under, "Test Procedure: 9. Transfer 50 uL of the diluted specimens to the labeled GAS Reaction Tube, mix the solution by pipetting up and down 3 to 5 times and close the cap, and transfer 50 uL of the same specimen to the labeled Strep C/G Reaction Tube, mix the solution by pipetting up and down a minimum of 3 to 5 times, close the cap. The solutions should be clear and free of solid material." And; "Limitations: The main laboratory technique required is pipetting. Good laboratory technique is essential for

	the proper performance of this assay ..." 4. Review of patient records for the patient run of Quidel Solana Streptococcus exams performed on September 10, 2019 revealed the following: Patient Alias 1 Date of Birth: 11-30-2013 Group A Strep: Positive Group CG Strep: Positive Patient Alias 2 Date of Birth: 10-25-2017 Group A Strep: Negative Group CG Strep: Negative Patient Alias 3 Date of Birth: 11-27-2012 Group A Strep: Negative Group CG Strep: Invalid Patient Alias 4 Date of Birth: 06-30-2014 Group A Strep: Negative Group CG: Negative Patient Alias 5 Date of Birth: 05-07-08 Group A Strep: Negative Group CG: Negative Patient Alias 6 Date of Birth: 07-27-2012 Group A Strep: Negative Group CG: Negative 5. Interview with Testing Personnel #2 (as listed on Form CMS-209) in the laboratory on 09/10/2019 confirmed the findings. He confirmed that sometimes he would get invalids and like this time, the test has to be repeated. Key: CMS - Centers for Medicare and Medicaid Services 42141 A. Based on surveyor observation, manufacturer's instructions, patient results and confirmed in interview of facility personnel, the laboratory failed to follow manufacturer's instruction for cleaning the Solana instrument. The findings were: 1. Surveyor observation made in the laboratory on 09/10/2019 at 13:45 hours revealed Testing Personnel #2 (as listed on Form CMS-209) cleaned the Solana with Sodium Chloride solution using a cotton swab. 2. Review of the manufacturer's instructions under "Maintenance and Cleaning" UM2027801EN00 (12/15) it states "Solana should be cleaned regularly. Use a damp cloth to clean the Solana. If dirt is persistent, rub the surface of the Solana with a cloth that has been moistened with pure alcohol (isopropanol or ethanol). Do not use aggressive cleaning agents such as acetone. If the inside of the Solana is contaminated, please contact Quidel Technical Support: 800.874.1517. For more persistent stains and for disinfecting the instrument, it is possible to clean the surface with a cloth dipped in 10% bleach solution followed by wiping with water. The procedure can be repeated 2 to 3 times. It its also possible to use the 70% alcohol to wipe off the remaining traces of bleach. Spillage of potentially infectious material should be wiped off immediately with absorbent paper tissue and the contaminated areas wiped with 10% bleach solution. Materials used to clean spills, including gloves, should be disposed of as biohazardous waste." 3. The laboratory failed to follow the manufacturer's instructions when cleaning the Quidel Solana analyzer. 4. Review of patient records for the patient run of Quidel Solana Streptococcus exams performed on September 10, 2019 revealed the following: Patient Alias 1 Date of Birth: 11-30-2013 Group A Strep: Positive Group CG Strep: Positive Patient Alias 2 Date of Birth: 10-25-2017 Group A Strep: Negative Group CG Strep: Negative Patient Alias 3 Date of Birth: 11-27-2012 Group A Strep: Negative Group CG Strep: Invalid Patient Alias 4 Date of Birth: 06-30-2014 Group A Strep: Negative Group CG: Negative Patient Alias 5 Date of Birth: 05-07-08 Group A Strep: Negative Group CG: Negative Patient Alias 6 Date of Birth: 07-27-2012 Group A Strep: Negative Group CG: Negative 4. Interview with Testing Personnel #2 (as listed on Form CMS-209) in the laboratory on 09/10/2019 confirmed the findings. He confirmed that he would clean the reaction holes with a cotton swab and Sodium Chloride solution.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:

	Based on surveyor observation and confirmed personnel interview, the laboratory failed to ensure expired items were not available for use. The findings were: 1. Direct observation during tour of the laboratory on 09/10/19 at 09:00 hours, revealed the following: Gold blood collection BD Vacutainer tubes (Ref 367989) Quantify: 1 unopened pack of 100 Lot number 8225985 Expiration date 2019-08-31 2. Interview with technical consultant on September 10, 2019 at 09:00 hours confirmed findings. Key BD- Becton Dickinson Ref- Reference
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory verification records and confirmed in interview of facility personnel, the laboratory failed to review and evaluate verification studies prior to testing patients on 2 of 2 Quidel Solana molecular analzyers implementeed in October 2017. The findings were: 1. Surveyor observation made on August 10, 2019 during the initial tour of the facility revealed the laboratory had 2 Quidel Solana molecular analyzers available for patient testing. Instrument 1 (Serial Number 17020710) Instrument 2 (Serial Number 15020248) 2. Review of laboratory verification records for 2 of 2 Quidel Solana molecular analyzers revealed that in October 2017, the laboratory ran verification panels on each of the analyzers. However, prior to patient testing, the laboratory failed to review and evaluate the raw verification data. The verification data had not been reviewed and evaluated as of the date of the survey, September 10, 2019. 3. The findings were confirmed in interview of the technical consultant on September 10, 2019 at 11:30 hours in the office.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, manufacturer's instructions, maintenance records and confirmed in interview of facility personnel, the laboratory failed to have documentation of performing weekly, monthly and quarterly maintenance according to the manufacturer's instructions for the Sysmex automated hematology analyzer. The findings were: 1. A review of the laboratory policy "Instrument Operation and Maintenance" states "Maintenance of each piece of laboratory instrumentation shall be in accordance with manufacturer's recommendations. Document all maintenance performed on the test systems in use. Also document repairs and remedial action on

	all test systems." 2. A review of the instrument operator manual Sysmex Automated Hematology Analyzer XP-300 (revision May 2014) states: Weekly - Clean SRV Tray Monthly - Clean Transducer and waste chamber Quarterly - Clean SRV 3. A review of the laboratory's hematology maintenance records from August 2017 to May 2019 revealed the laboratory failed to document the following maintenance May 2018 Monthly maintenance not documented October 2018 Weekly maintenance (4 out of 4 weeks not documented) March 2019 Quarterly maintenance not documented July 2019 Quarterly maintenance not documented September 2019 Weekly maintenance (1 of 4 weeks missing) Monthly maintenance not documented 4. An interview with the technical consultant on 09/10/2019 at 14:00 hours in the office after her review of the records, confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of quality control records, review of the laboratory's submitted Form CMS-116, and confirmed in interview of facility personnel, the laboratory failed to perform a positive and negative quality control each day of patient testing for the Quidel Solana. The findings were: Note: The laboratory's IQCP (Individual Quality Control Plan) study was performed on a previous Solana analyzer that is no longer located at the facility. The laboratory did not perform IQCP studies for the current two Solana analyzers in use. Therefore, the laboratory did not develop IQCP studies and must perform external positive and negative quality control each day of patient testing. 1. Review of the laboratory's policy titled, "Control Policy" approved by the laboratory director on March 3, 2006, it stated, "For qualitative testing, the laboratory will include a positive and negative control on every day of use of each qualitative procedure." 2. Review of the laboratory's quality control records from January 1, 2019 to September 10, 2019 revealed that external quality control was performed as follows: Instrument 1 (Serial Number 17020710) January 11, 2019 January 31, 2019 February 20, 2019 March 8, 2019 March 20, 2019 March 29, 2019 May 2, 2019 May 16, 2019 June 13, 2019 July 3, 2019 July 24, 2019 September 6, 2019 Instrument 2 (Serial Number 15020248) January 9, 2019 February 28, 2019 March 7, 2019 March 20, 2019 March 29, 2019 May 2, 2019 May 16, 2019 June 13, 2019 July 3, 2019 July 24, 2019 September 6, 2019 3. According to the submitted CMS Form-116, the laboratory performs 2,400 bacteriology exams annually. See attached Patient Alias List for patients tested from January 1, 2019 to September 10, 2019 when an external positive and negative quality control was not performed each day of patient testing. 4. The findings were confirmed in interview of the technical consultant on September 10, 2019 at 13:30 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services
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 quality assurance records, review of hematology calibration records, and confirmed in interview of facility personnel, the laboratory's quality assurance program failed to identify and correct that calibration raw data had not been retained with the service report. The findings were: 1. Review of the laboratory's quality assurance report dated September 5, 2018, it stated, "The following is a lab quality assessment report for the month of August 2018." and; "Calibration: XP-300: Calibration was performed 08/18. All calibration records were reviewed and approved. The next calibration is due 02/19. 2. Review of the laboratory's calibration records from July 2017 to August 2019 revealed Sysmex XP-300 calibrations were performed as follows: July 25, 2017 January 19, 2018 July 6, 2018 (incomplete records) December 26, 2018 June 4, 2019 3. Review of the calibration records performed on July 6, 2018 revealed there was no documentation that the calibration records were reviewed or approved or that the raw data was not retained. The BeyondCare Report stated, " ...Resolution: PM and calibration have been completed. The Certificate of Calibration was placed in the instrument's service log book. Next PM is due (Jan 2 2018) [sic]." 4. The laboratory's quality assurance plan failed to identify that calibration records had not been retained. 5. Interview with Testing Personnel #4 (as listed on Form CMS-209) at 15:00 hours in the office confirmed the findings. She stated that she had requested the records from the company but they had not provided the records. She went on to say they had a different technician this time. Key: PM - preventative maintenance CMS - Centers for Medicare and Medicaid Service
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 laboratory policy, patient final reports and confirmed in interview of facility personnel, the laboratory failed to ensure 8 of 10 final patient reports were documented in the patient chart. Findings included: 1. Review of laboratory policies: a " Test Records" stated "Reports and logs must be organized as to allow for ready access to reports. Test results should be reported promptly to requester and released only to authorized persons." b. "Quality Assurance Plan" states under "Patient Test Management" (Post-Analytical) "That the report contains information the physician needs to interpret the results, and that the results arrive to the physician in a timely fashion, and that the lab results match the posted results on the patient chart." 2. Random review of 10 patient records from August 29, 2019 to August 30, 2019 revealed the laboratory failed to ensure patient final reports were available on 8 out of 10 records reviewed. Patient Alias 1 tested 8/29/2019 14:29 Patient Alias 2 tested 8/29 /2019 14:30 Patient Alias 3 tested 08/30/2019 10:00 Patient Alias 4 tested 08/30/2019 10:01 Patient Alias 5 tested 08/30/2019 11:05 Patient Alias 6 tested 08/30/2019 11:07 Patient Alias 7 tested 08/30/2019 17:11 Patient Alias 8 tested 08/30/2019 17:12 3. An

	interview with the technical consultant on 9/10/2019 at 14:00 hours in the office confirmed the findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of verification records, and confirmed in interview of facility personnel, the laboratory director failed to ensure verification studies were complete prior to patient testing. The findings were: 1. Review of the laboratory's policy titled, "Validation of a New Test System" no approval date by the laboratory director stated, "Purpose: The purpose of this policy is to ensure that prior to performing tests on patients, every new test system will have studies performed to validate the accuracy, precision, reportable range of test results, and verify manufacturer's normal values." 2. Review of the verification studies for the laboratory's two Quidel Solana analyzers revealed the verification records were not signed by the laboratory director. 3. The findings were confirmed in interview of the technical consultant on September 10, 2019 at 11:10 hours.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, patient results, and confirmed in interview of facility personnel, the laboratory director failed to ensure testing personnel are performing test methods as required for accurate and reliable results. The findings were: 1. Surveyor observation made on 09/10/2019 at 13: 44 hours revealed Testing Personnel #2 (as listed on Form CMS-209) performing a patient run of Quidel Solana Streptococcus A and Quidel Solana Streptococcus C & G. While performing the step of placing the reaction vessels into the analyzer using the transfer rack, he dropped both sets of reaction tubes. He proceeded to pick them both up and place them into the analyzer. 2. Review of patient records for the patient run of Quidel Solana Streptococcus exams performed on September 10, 2019 revealed that for one patient a positive for Group A and C/G were obtained and for one patient the CG panel was invalid: Patient Alias 1 Date of Birth: 11-30-2013 Group A Strep: Positive Group CG Strep: Positive Patient Alias 3 Date of Birth: 11-27-2012 Group A

	Strep: Negative Group CG Strep: Invalid 3. Interview with Testing Personnel #2 (as listed on Form CMS-209) in the laboratory on 09/10/2019 confirmed the findings. He confirmed that sometimes he would get invalids and like this time, the test has to be repeated. Key: CMS - Centers for Medicare and Medicaid Services
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, patient results, and confirmed in interview of facility personnel, the technical consultant failed to identify training needs for testing personnel. The findings were: 1. Surveyor observation made on 09/10/2019 at 13:44 hours revealed Testing Personnel #2 (as listed on Form CMS-209) performing a patient run of Quidel Solana Streptococcus A and Quidel Solana Streptococcus C & G. While performing the step of placing the reaction vessels into the analyzer using the transfer rack, he dropped both sets of reaction tubes. He proceeded to pick them both up and place them into the analyzer. 2. Review of patient records for the patient run of Quidel Solana Streptococcus exams performed on September 10, 2019 revealed that for one patient a positive for Group A and C/G were obtained and for one patient the CG panel was invalid: Patient Alias 1 Date of Birth: 11-30-2013 Group A Strep: Positive Group CG Strep: Positive Patient Alias 3 Date of Birth: 11-27-2012 Group A Strep: Negative Group CG Strep: Invalid 3. Interview with Testing Personnel #2 (as listed on Form CMS-209) in the laboratory on 09/10/2019 confirmed the findings. He confirmed that sometimes he would get invalids and like this time, the test has to be repeated. Key: CMS - Centers for Medicare and Medicaid Services