Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2042515	01/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bee Caves Pediatrics,Pa	2501 Rr 620 South, Suite 220, Lakeway, 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
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 proficiency testing (PT) records and interview, the laboratory failed to sign the attestation statement attesting that proficiency testing samples were handled in the same manner as patient testing for 3 of 6 Microbiology events and 2 of 6 Hematology events. Findings follow. A. Review of the American Proficiency Institute (API) proficiency testing records from the 1st, 2nd and 3rd events of 2019 and 2020 showed the three Microbiology events in 2020 were lacking signed testing personnel attestation statements for Throat Cultures reporting Positive or Negative for Group A Strep. Review of the Attestation Statement page stated, "The undersigned certify that, as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens." 1. Review of the 1st event of 2020 showed no signatures for specimens TH-03, TH-04, and TH-05. A note was documented by the Technical Consultant (TC) to "see Daily Log" and "the employee [was] no longer here." 2. Review of the 2nd event of 2020 showed no signature for specimens TH-06, TH-07, TH-08, TH-09, and TH-10. A note was documented by the TC to "see Daily Log (again)." 3. Review of the 3rd event of 2020 showed no signatures for specimens

	TH-011, Th-12, Th-13, Th-14, and TH-15. A note was documented by the TC "testing personnel no longer at clinic." B. Review of the API proficiency testing records from the 1st, 2nd and 3rd events of 2019 and 2020 showed the 1st and 2nd events in Hematology 2020 were lacking signed testing personnel attestation statements for Hematocrit, Hemoglobin, Lymphocytes, Mid, Granulocytes, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Mean Corpuscular Volume, Platelet Count, Red Cell Count, White Cell Count. Review of the Attestation Statement page stated, "The undersigned certify that, as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens." 1. Review of the 1st event of 2020 showed no signatures for specimens HSY-03, HSY-04, HSY-05. A note was documented by the Technical Consultant (TC) that the employee was "no longer here." 2. Review of the 2nd event of 2020 showed no signature for specimens HSY-06, HSY-07, HSY-08, HSY-09, and HSY-10. A note was documented by the TC to "see individual print-outs...daily log initials." C. Interview with the TC on the CMS form 209 on January 12, 2021 in the patient room acknowledged testing personnel were no longer here and the problems were not identified until her review and the problem had been discussed with the clinic manager.
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: I. Based on review of the manufacturer's package insert, laboratory's procedure, reagent logs, interview, and patient testing records, the laboratory failed to follow the test procedure for Throat Cultures when they obtained and used the wrong plates to identify positive or negative for Group A Strep. Findings follow. A. Review of the Strep Select Agar package insert under III. Principles of the Procedure stated, "growth support characteristics of Strep Select Agar are derived from the presence of peptones prepared from pancreatic digest of casein and soybean meal. Sheep blood provides both X factor (hemin) and a visualization of hemolytic reactions. Colistin and nalidixic acid, antimicrobial agents, create a selective environment for gram positive organisms by either disrupting the cell membrane or blocking DNA replication of susceptible gram-negative organisms." and under II. Summary and Explanation stated, "This medium was described by Roantree et al for the isolation of Group A streptococci. Differentiation may be accomplished by characteristics such as Beta hemolysis, inhibition by 0.04 unit bacitracin discs and/or serological tests. Sheep blood is incorporated for determination of hemolytic activity." B. Review of the laboratory's procedure titled Throat Culture Screen, approved on 1/11/2016, stated, "Presumptive identification of Group A Streptococcus is easily made by demonstrating the inhibition of growth of the organism around a 0.04 unit bacitracin disk. The method of choice is to test pure culture isolates or to utilize a Strep selective media." Under Materials Required listed, "Group A Selective Strep Agar with 5% Sheep Blood". C. Review of the laboratory's documentation of agar plates received in the laboratory contained Hardy Diagnostic Blood Agar Plates, Lots 438742 and 442373, and indicated 3 and 4 packages (of 10 plates per package) were received, respectively. Documentation of the error on the back side of the page stated, "6/12/19

	- 9/03/19 was using Blood Agar plates. 9/03/19 noticed wrong plates and order Strep Select Agar will switch once received new plates - RY." D. Interview with the Technical Consultant on the CMS form 209 on January 12, 2021 at 1110 in the patient room confirmed Blood Agar plates were used instead of Strep Selective plates. E. Review of patient testing logs for Throat Cultures from 6/12/2019 - 9/03/2019 showed 85 patients were tested. The laboratory routinely tested 2 patients per plate. Below is a partial list of patients tested as listed by dates of testing with the number of patients tested (see testing log): 1. 06/14/2020: 3; 2. 06/17/2020: 6; 3. 06/18/2020: 2; 4. 06/19 /2020: 1; 5. 06/20/2020: 1. II. Based on review of the manufacturer's instructions, the laboratory's policy and procedure, patient test reports, and interview, the laboratory failed to redact test results on the Complete Blood Count (CBC) using the Medonic M-series Hematology analyzer when flags were obtained on 3 out of 6 CBC patient test reports. A. Review of the Medonic M-series User Manual under 9.2 System Information Messages starting on page 70 stated, "The system software monitors a number of analytical and system functions and will display information that indicates the possible attention of the operator. This information will alert the operator to check the system or sample or institute selected troubleshooting procedures. This information is presented on the touch screen as a code next to one or more parameters." The various flags listed indicated the sample must be "re-analyzed" or was "too old or pathological sample". B. Review of the laboratory's CBC Medonic M-Series procedure, version 6/12, stated under Patient Testing "5. Report results according to standard laboratory policy. NOTE: ... See the User's Manual (pages 69-74) for out of range and message descriptions." With a hand-written addendum which stated, "TM, BD, NM, OM Flags may indicate possible sample/result problem and should not be reported. Recollect or send to reference lab. Cross result out on report and do not report in EMR." C. Review of 3 of 6 CBC test reports showed all the reports with flags were reported as identified below by patient initials and insturment sequence number: 1. 12/02/2020: # 3887; 2. 10/08/2020: #3664; 3. 10/07/2020: #3658. D. Interview with the Technical Consultant on the CMS form 209 on January 12, 2021 at 1300 in the patient room confirmed indicies with flags were reported. KEY: EMR - Electronic Medical Record
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 manufacturer's instructions, maintenance records and interview, the laboratory failed to document maintenance on the Medonic Hematology analyzer for Complete Blood Counts (CBCs) for 4 of 12 months reviewed. Findings follow. A. Review of the Medonic M-series User's Manual Section 8: Cleaning, Maintenance & Transport section of the manual on page 64 under 8.2 Monthly Cleaning stated, "This section describes the cleaning procedure to be used to secure the correct function of the instrument on a monthly basis" and described the Cleaning Procedure and Clot Prevention. Under Clot Prevention also stated, "this process will decrease the risk of debris material building up in the instrument system. This should be performed at least once a month or every 1000 samples." B. Review of the Maintenance Log for Medonic M-Series showed no documentation of the monthly maintenance: Clean Procedure and Clot Prevention for the months of January, April, May, and July of

	2020. C. Interview with the Technical Consultant on the CMS form 209 on January 12, 2021 in the patient room acknowledged she will review with testing personnel #1 on the CMS form 209 and make sure she is on track.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the patient test reports and interview, the laboratory failed to ensure the laboratory included the name of the laboratory where the test was performed on 5 out of 11 test reports reviewed. A. Review of 5 of 11 patient test reports showed all 5 Throat Culture test reports did not include the name of the laboratory where the testing was performed. The following Throat Culture test reports by accession number were reviewed: #797764, 807008, 819394, 820103, and 831597. B. Interview with the Technical Consultant on the CMS form 209 on January 12, 2021 at 1240 in the patient room confirmed the test reports were missing the name of the facility.