Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0667703	08/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bee Caves Pediatrics Pa	2499 S Capital Of Texas Highway, Austin, 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
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 instructions, laboratory policy and procedure, patient test report and interview, the laboratory failed to redact flagged indices on the Complete Blood Count (CBC) test report for 2 out of 3 patient test reports reviewed. A. Review of the Medonic M-Series User's 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... System Information Messages... 1. Indicator Description SE The rate of cell pulses per time unit varies too much. Possible reasons might be clogging, air bubbles, electrical disturbances or difficult to lyse. Action Re-analyze sample... 2. Indicator Description BD The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." B. Review of the laboratory's policy and procedure titled CBC Medonic M-Series, revision 01/12/2021, under Procedure Patient Testing stated, "7. Report patient testing results. a. It is the responsibility of the Provider to correlate instrument results (including flagged parameters) with clinical findings. See the User's manual (pages 71-76) for system information message descriptions. Some flags and the Diff flags (BD, NM, OM, and TM) indicate a possible problem with the accuracy of the results and should not be

	reported. If directed by the Provider, collect a new sample and repeat the testing. If the flag is still present or if the sample is not redrawn, then the flagged result(s) must be marked through with a single dark line on the printed report and the results should not be entered in the EMR. " C. Review of 6 patient reports, showed 3 had flagged indices. Of the 3 test reports with flagged indices, 2 had been reported (not redacted) and entered in the EMR. 1. On 05/05/2021, sample at sequence #1810 was flagged with SE for the WBC (White Blood Cell Count) and was also reported in the EMR. 2. On 03/03/2021, sample at sequence #1402 was flagged with BD for the LYM (absolute Lymphocytes), MID (absolute Monocytes, mixed), GRAN (absolute granulocytes), LYM% (percent Lymphocytes), MID% (percent Monocytes, mixed), GRA% (percent Granulocytes), and was also reported in the EMR. D. Interview with the technical consultant on August 19, 2021 at 1228 hours confirmed the indices with flags were reported and entered into the EMR. KEY: EMR = Electronic Medical Record
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: I. Based on review of the manufacturer's instructions, bacitracin quality control (QC), patient testing logs and interview, the laboratory failed to ensure the bacitracin discs used for the differentiation of Group A Streptococcus for 20 throat culture screens had not exceeded their expiration date. Findings follow. A. Review of the BD BBL Taxo A Discs for Differentiation of Group A Streptococci package insert under intended use stated, "BD BBL Taxo A discs are for the presumptive identification of group A beta-hemolytic streptococci based on susceptibility to a low level of bacitracin." B. Review of the Bacitracin Quality Control Record from 01/02/2020 - 06/28/2021 showed Bacitracin Lot 9092634 expired on 10/31/2020, and the new lot was QC'd on 11/11/2020. C. Review of the Daily Testing Log from 11/01/2020 - 11/10/2020 showed 20 throat cultures were set up. D. Interview with the technical consultant on August 19, 2021 at 1040 in the patient room confirmed the bacitracin used to set up throat culture screens was expired. II. Based on review of the media receipt log, patient testing logs, and interview, the laboratory failed to ensure the Selective Strep Agar plates used to set up 6 throat culture screens for Group A Streptococcus had not exceeded their expiration date. Findings follow. A. Review of the Media Receipt Log reviewed from 01/15/2021 - 08/04/2021 showed the Hardy Diagnostics Selective Strep Agar, Lot 475930 expired on 3/21/2021, and the new Lot 134875 was not received until 03/24/2021. B. Review of the Daily Testing Log from 03/22/2021 - 03 /23/2021 showed 6 throat cultures were set up. C. Interview with the technical consultant on August 19, 2021 at 1035 in the patient room confirmed the plates used to set up the throat cultures were expired.