Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315202	11/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Family Allergy & Asthma, Psf, Pllc	6401 Poplar Avenue Suite 300, Memphis, TN	

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
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, patient test reports, and interview with testing personnel number one, the laboratory failed to participate in proficiency testing for the red blood cell count, hemoglobin, hematocrit and platelet count in 2017 and 2018. The findings include: 1. Review of the laboratory's proficiency testing records for 2017 and 2018 revealed the laboratory only reported white blood cell (WBC)and WBC differential to the laboratory's proficiency testing program. The laboratory indicated to the proficiency testing program no patient testing for the red blood cell, hemoglobin, hematocrit and platelet count. 2. Review of the laboratory's patient test reports for patient numbers two (reported 7.10.17) three (reported 12.21.17,) four (reported 3.7.18), five (reported 8.31.18) and six (reported 11.08.18), revealed a scanned copy of the complete blood count results maintained in the patient electronic medical record (EMR). 3. Interview with testing personnel number one on November 13, 2018 at 5:00 pm via electronic mail confirmed the laboratory retains the instrument printout with the complete CBC results in the EMR as part of the patient record and did not participate in proficiency testing for the red blood cell, hemoglobin, hematocrit and platelet count in 2017 and 2018.

D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: The laboratory failed to evaluate nongraded proficiency testing scores (Refer to D5215), failed to document complete blood count (CBC) instrument background counts (Refer to D5431), failed to detect and correct problems with complete blood count records retention (Refer to D5791 citation number one), failed to detect and correct problems with CBC quality control performance (Refer to D5791 citation number two).
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's 2017 and 2018 proficiency testing evaluation reports and interview with the technical consultant, the laboratory failed to verify the accuracy of white blood cell count (WBC) and WBC differential when the proficiency testing program assigned an artificial score and the laboratory did not evaluate the nongraded proficiency testing scores in 2017 and 2018. The findings include: 1. Review of the laboratory's proficiency testing evaluation reports revealed an artificial score of 100% with the code [20] "No appropriate target/response cannot be graded" for the WBC and WBC differential for events FH3-C 2017, FH3-A 2018, FH3-B 2018, and FH3-C 2018. There was no self-evaluation of any of the scores to determine accuracy of the results. 2. Interview with the technical consultant on November 8, 2018 at 4:30 pm confirmed there was no quality assessment performed to verify the accuracy of the artificial 100% for the WBC and WBC differential for 2017 event 3, and 2018 events 1, 2, and 3.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance records for the Abbott Cell-Dyn Emerald 22 complete blood count (CBC) instrument and interview with the technical

	consultant the laboratory failed to document daily background counts for the Cell-Dyn Emerald 22 complete blood count (CBC) instrument for at least 2 years in 2017 and 2018. The findings include: 1. Review of the laboratory's maintenance records revealed no documentation of the background counts for the Abbott Cell-Dyn Emerald 22 CBC instrument from April 24, 2017 to August 7, 2018 with patient testing performed. 2. Interview with the technical consultant on November 8, 2018 at 4:30 pm confirmed the laboratory did not maintain the daily instrument background count instrument printouts for the Abbott Cell-Dyn Emerald 22 CBC instrument from April 24, 2017 to August 7, 2018.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Citation number one Based on observation of the laboratory, review of the laboratory's quality control records for the Abbott Cell-Dyn Emerald 22 complete blood count (CBC) instrument from April 19, 2017 to August 8, 2018, the laboratory's 2017 and 2018 quality assessment records, patient test reports and interview with the technical consultant, the laboratory's quality assessment was ineffective when it failed to detect and correct problems with quality control retention in 2017 and 2018 with patient testing performed. The findings include: 1. Observation of the laboratory on November 8, 2018 at 9:00 am revealed the Abbott Cell-Dyn Emerald 22 instrument (serial # 250216-000236) in use for patient testing for white blood cell count (WBC) and WBC differential patient testing. 2. Review of the laboratory's quality control records for the Abbott Cell-Dyn Emerald 22 instrument revealed the laboratory did not maintain the low, normal, and high quality control results for the wbc differential absolute counts from April 19, 2017 to August 7, 2018; and the complete blood count (CBC) low, normal and high quality control results were not maintained from June 29, 2018 to August 7, 2018 as follows: Lot 7079 in use from 04.19.17 to 06.01.17 - No WBC absolute counts retained Lot 7135 in use from 06.01.17 to 07.28.17 - No WBC absolute counts retained Lot 7191 in use from 07.25.17 to 09.22.17 - No WBC absolute counts retained Lot 7247 in use from 09.21.17 to 11.17.17 - No WBC absolute counts retained Lot 7303 in use from 11.13.17 to 01.11.18 - No WBC absolute counts retained Lot 7359 in use from 01.08.18 to 03.09.18 - No WBC absolute counts retained Lot 8050 in use from 03.05.18 to 05.04.18 - No WBC absolute counts retained Lot 8106 in use from 04.30.16 to 06.29.18 - No WBC absolute counts retained Lot 8162 in use from 06.29.18 to 08.07.18 - No CBC quality control records retained 3. Review of the laboratory's quality assessment records for 2017 and 2018 revealed review of quality control on dates of 6.30.17, 9.30.17, 12.29.17, 3.30.18, 6.29.18 by the former technical consultant and 8.6.18, 9.4.18, 10.23.18, 11.8.18 by the current technical consultant. No corrective action was documented for the lack of retention of the WBC differential absolute counts or lack of retention of CBC quality control in 2017 and 2018. 4. Review of patient reports for patient number two (dated 7.10.17), three (dated 12.21.17) and four (dated 3.7.18) revealed patient reporting for CBC. 5. Interview with the current technical consultant on November 8, 2018 at 4:30 pm confirmed the laboratory's quality assessment was ineffective when it failed to detect CBC QC record retention errors, correct and

	document corrective actions in 2017 and 2018. _____ Citation number two Based on review of the Abbott Cell-Dyn Emerald 22 complete blood count (CBC) instrument operator's manual, patient number five test report and interview with the technical consultant, the laboratory's quality assessment process failed to detect that two levels of CBC QC were not performed wiht patient testing on August 31, 2018. 1. Review of the Abbott Cell-Dyn Emerald 22 CBC instrument operator's manual revealed the following statement: "Before running patient specimens, run a minimum of two levels of controls." 2. Review of patient number five test report revealed patient testing for CBC on 8.31.18. 3. Review of the laboratory's CBC quality control records revealed that two levels of quality control were not performed on 08.31.2018. 4. Review of the September 4, 2018 quality assessment documentation records revealed review of the August 31, 2018 CBC QC records with no documented corrective action. 5. Interview with the technical consultant on November 8, 2018 at 4:30 pm confirmed the laboratory's quality assessment process was ineffective when it failed to detect, correct and document corrective action for CBC failures.
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 review of the Centers for Medicare and Medicaid Services Personnel Report (CMS 209), training documents for the Abbott Cell-Dyn Emerald 22 complete blood count (CBC) instrument, and interview with the technical consultant, the technical consultant failed to ensure all personnel received training for the Abbott Cell-Dyn Emerald 22 CBC instrument in 2017. The findings include: 1. Review of the CMS209 form revealed three testing personnel. 2. Review of the training documents for the Cell-Dyn Emerald 22 CBC instrument revealed no documented training for testing personnel numbers two and three. 3. Interview with the technical consultant on November 8, 2018 at 4:30 pm confirmed testing personnel numbers two and three perform patient CBC testing using the Abbott Cell-Dyn Emerald 22 instrument, with no documented training, beginning April 24, 2017.