Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D0887043	**(X3) Date Survey Completed** 07/24/2018
Name of Provider or Supplier Physicians Of Family Medicine	**Street Address, City, State** 13861 Hull Street Road, Midlothian, VA	
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	An announced CLIA validation survey was conducted at Physicians of Family Medicine on July 24, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of hematology quality control (QC) records and an interview, the laboratory failed to retain hematology QC records for three (3) of twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's Abbott Emerald hematology QC records from July 2016 through the date of the survey on July 24, 2018 revealed no records for: February 2017, March 2017, May 2017. The inspector requested to review the QC data listed above. No data was available to review. The primary testing personnel stated: "I will try to contact Abbott to see if I can retrieve the data from uploads, but I do not have the documentation at this time". 2. The inspector requested to review the Abbott Emerald manufacturer's information sheets for the control materials used in the timeframe outlined above. The documentation was not available for review. The primary testing personnel stated: "we did not keep those print outs but have started retaining all copies now". 3. In an interview with the primary testing personnel at approximately 4:30 PM, it was confirmed that the laboratory failed to retain hematology instrument QC print out records and manufacturer's assay information package inserts for three (3) of twenty-four (24) months reviewed.

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 a review of manufacturer's Operations Manual, hematology instrument maintenance records, and an interview, the laboratory failed to perform and document hematology instrument semi-annual maintenance in calendar years 2016, 2017, and up to the date of the survey on July 24, 2018. Findings include: 1. Review of the Abbott Emerald Operations Manual revealed manufacturer's instructions to "perform the Lubricating Syringe Pistons procedure semi-annually". 2. Review of the laboratory's Abbott hematology maintenance logs revealed no semi-annual maintenance documented in calendar years 2016, 2017, and up to 7/24/18. The inspector requested the documentation. The primary testing personnel stated: "we have not performed the semi-annual maintenance. We will ask Abbott field service to come in to train us or we will review the training CD to do this procedure". 3. In an interview with the primary testing personnel at approximately 4:30 PM, it was confirmed that the laboratory failed to perform and document the Abbott Emerald semi-annual preventative maintenance in 2016, 2017, and 2018.
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 procedures and policies, hematology calibration records, and an interview, the laboratory failed to document calibration procedures for Complete Blood Count (CBC) patient testing according to their written procedure in calendar year 2016. Findings include: 1. Review of the laboratory's procedure manual revealed a Quality Assurance (QA) policy that outlined to calibrate CBC testing at a frequency of every six (6) months. 2. Review of the laboratory's Abbott Emerald hematology instrument calibration documentation from April 2016 to the date of the inspection on 7/24/18, a total of twenty-six (26) months, revealed the following seven (7) month lapse in CBC calibration: The inspector noted documentation of calibration checklist and procedures on 4/4/16, 5/19/17, 11/7/17, and 5/18/18. The inspector requested to review additional calibration records for the Emerald analyzer in calendar year 2016. No additional calibration checklist records were available. 3. In an interview with primary testing personnel at approximately 4:30 PM, it was confirmed that the

	laboratory failed to document calibration procedures for CBC testing, in calendar year 2016, according to their written QA policy resulting in a calibration lapse of seven (7) months as outlined above.
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: Based on review of policies and procedures, Quality Control (QC) monthly reports, and an interview, the laboratory failed to follow a written policy for hematology QC review for six (6) of the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's policies and procedures revealed a quality assurance (QA) plan to monitor, assess and correct problems with the Abbott Emerald hematology analyzer by performing a monthly review of Levy Jennings (LJ) reports. 2. Review of the laboratory's monthly hematology QC reports from July 2016 through the date of the survey on July 24, 2018 revealed no review of LJ statistics in January, February, March, April, May, and November of calendar year 2017. No additional Hematology QC statistics review was available upon request. 3. In an interview with the primary testing personnel at approximately 4:30 PM, it was confirmed that the laboratory failed to follow their written policy to review QC reports in order to monitor, assess and correct problems with the Abbott Emerald hematology analyzer for the timeframe outlined above in 2017.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, quality assurance (QA) records, and an interview, the laboratory failed to maintain a mechanism to ensure the accuracy of manually transcribed patient Complete Blood Count (CBC), Wet Prep, and Urine Sediment microscopy examination results from July 2016 to the date of the survey on July 24, 2018. Findings include: 1. During a tour at approximately 1:00 PM, a conversation with the primary testing personnel revealed that patient CBC, Wet Prep, and Urine Sediment microscopy results are manually transcribed from patient test logs and instrument print outs into the laboratory's eClinical electronic medical record by the testing personnel staff. 2. Review of the laboratory's procedure manual revealed a quality assurance (QA) plan that stated: "the lab will monitor and correct problems in the laboratory with QA checks for accuracy of manually transcribed computer entries which will be compared to the specimen logs". 3. Review of all available QA documentation and logs from 2016, 2017, and year to date in 2018, revealed no evidence of accuracy checks or review of manually transcribed patient results. No chart review or periodic quality audits were available for review upon request. 4. In an

	interview with the primary testing personnel at approximately 4:30 PM, it was confirmed that the laboratory failed to follow their written QA policy to ensure the accuracy of manually transcribed patient Complete Blood Count (CBC), Wet Prep, and Urine Microscopy results for twenty-four (24) of twenty-four (24) months reviewed.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the policies and procedures, manufacturer's Operation Manual, maintenance logs, hematology quality control (QC) records, and an interview, the laboratory director failed to ensure that the quality assurance (QA) policies were maintained during the twenty-four (24) months of July 2016 to the date of the survey on July 24, 2018. Findings include: 1. The laboratory failed to perform and document the Abbott Emerald semi-annual preventative maintenance in calendar years 2016, 2017, and 2018 (Cross Reference D 5429). 2. The laboratory failed to document calibration procedures for hematology Complete Blood Count (CBC) patient testing according to their written procedure in calendar year 2016 (Cross Reference D 5437). 3. The laboratory failed to follow their written policy to review AC reports in order to monitor, assess and correct problems with the Abbott Emerald hematology analyzer for six (6) of twelve (12) months in calendar year 2017 (Cross Reference D 5791). 4. The laboratory failed to maintain a mechanism to ensure the accuracy of manually transcribed patient Complete Blood Count (CBC), Wet Prep, and Urine Sediment microscopy examination results from July 2016 to the date of the survey on July 24, 2018 (Cross Reference D 5891).
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, test logs, and an interview, the technical consultant failed to perform annual competency evaluations for five (5) of sixteen (16) testing personnel (TP) in 2016 and 2017. Findings include: 1. Review of the CMS Form 209 with the lead testing personnel revealed that the laboratory director also performs the duties of technical consultant and that there are sixteen (16) testing personnel. 2. Review of the laboratory personnel files revealed that the following five (5) TP lacked a 2016 and 2017 annual competency evaluation: Testing Personnel A, Testing Personnel B, Testing Personnel C, Testing Personnel D,

	Testing Personnel E. (See Personnel Code Sheet) 3. A review of the laboratory test logs revealed that the testing personnel listed above perform Wet Prep and Urine Sediment microscopy examinations. 4. In an interview with the primary testing personnel at approximately 4:30 PM, it was confirmed that the technical consultant failed to perform Wet Prep and Urine Sediment microscopy competency evaluations for the five (5) testing personnel as outlined above.