Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0869535	06/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Southeast Idaho Family Practice	2775 Channing Way, Idaho Falls, ID	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to verify the accuracy of potassium hydroxide (KOH), urine sediment examinations, and post-vasectomy examinations at least twice annually since the last survey on September 28, 2016. Findings: 1. A record review revealed the laboratory failed to document the accuracy of KOH, post-vasectomy examinations, and urine microscopic examinations at least semiannually since the last survey. 2. An interview on June 28, 2018 at 8:55 AM, with the laboratory lead, confirmed the laboratory failed to perform and document the accuracy of KOH, urine microscopic and post-vasectomy examinations at least semiannually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on an observation of reagents in the laboratory refrigerator and an interview with the laboratory lead, the laboratory failed to label the expiration dates on the

	control vials for the Cell-Dyn Emerald complete blood count (CBC) analyzer as found at the time of the survey. Findings: 1. An observation of the laboratory refrigerator on June 28, 2018 at 10:00 AM revealed the Cell-Dyn CBC control vials failed to be labeled with the expiration dates. 2. An interview on June 28, 2018 at 10:05 AM, with the laboratory lead, confirmed the laboratory failed to label the CBC quality control vials with expiration dates.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to establish the number, type and frequency of reagent testing controls for the bacitracin test (A disk) used for the identification of Group A streptococci organisms and serum human chorionic gonadotropin (hCG) test since the last survey on September 28, 2016. Findings: 1. A review of the laboratory's Individualized Quality Control Plan (IQCP) and procedure for serum hCG testing revealed the quality control plan failed to include the number, type, and frequency of quality control reagents used to perform the identification of Group A streptococci from throat specimens and serum hCG pregnancy test since the last survey. 2. An interview on June 28, 2018 at 10:10 AM, with the laboratory lead, confirmed the IQCP and procedures failed to establish the number, type, and frequency of control reagents in the test system since the last survey.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records and an interview with the laboratory lead, the laboratory failed to rotate the testing of Cell-Dyn 18 Plus quality controls used on the Cell-Dyn Emerald complete blood count (CBC) analyzer among all testing personnel since the last survey on September 28, 2016. Findings: 1. A review of the quality control records from July 3, 2017 through May 18, 2018, for the Emerald CBC analyzer, revealed the laboratory lead performed the daily quality controls. 2. An interview on June 28, 2018, at 9:30 AM, with the laboratory lead

	confirmed that she was the only testing personnel who performed quality control tests for CBCs.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a quality control records review and an interview with the laboratory lead, the laboratory failed to meet the quality control requirements for the Cell-Dyn Emerald complete blood count (CBC) analyzer prior to reporting patient CBC results since the last survey on September 28, 2016. Findings: 1. A review of CBC quality control records from July 3, 2017 through May 18, 2018 revealed patient CBCs were reported for 4 days (8/4/2017, 2/20/2018, 2/16/2018, and 4/26/2019) when two out of three levels of controls were out of manufacturer's reference range. 2. An interview on June 28, 2018 at 9:45 AM, with the laboratory lead, confirmed the laboratory failed to verify the results of quality control testing were within the manufacturer's reference range prior to reporting patient CBC results.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to take corrective actions and evaluate patient complete blood count (CBCs) results when 2 out of 3 levels of quality control failed to meet the manufacturer's reference range on 8/4/2017, 2/16/2018, 2/20/2018, and 4/26/2019 for the Cell-Dyn Emerald CBC analyzer. Findings: 1. A review of quality control results and corrective action logs revealed the laboratory failed to take corrective actions and evaluate patient CBC test results when 2 out of 3 levels of quality control where outside the manufacturer's reference range. 2. An interview on June 28, 2018, at 10:10 AM, with the laboratory lead, confirmed the laboratory failed to take corrective actions and evaluate patient CBC results when quality control failed to meet the manufacturer's reference range.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and

	specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to identify and document the corrective actions for out of range temperatures for the refrigerator where quality controls materials for complete blood counts (CBCs) and microbiology media are stored from January through March 2018. Findings: 1. A record review of the laboratory refrigerator temperature chart revealed the range was 2 -8C. 2. The laboratory staff failed to identify and document corrective actions for the temperature documented below the range, at 1C, for 21 out of 31 days in January 10 out of 28 days in February, and 16 out of 31 days in March 2018. 3. An interview on June 28, 2018 at 9:55 AM, with the laboratory lead, confirmed the laboratory staff failed to correct and document the temperature for the refrigerator.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on records review and an interview with the laboratory lead, the laboratory director failed to ensure the quality control program for the Cell-Dyn Emerald complete blood count (CBC) test system, Group A streptococcus identification, and serum human chorionic gonadotropin (hCG) meets the CLIA requirements since the last survey on September 28, 2016. Refer to D5441, D5481, and D5783. Findings: 1. A quality control records review for the CBC test revealed the laboratory director failed to ensure a quality control program is monitored for the accuracy of control materials prior to patient test results reported. 2. A review of IQCPs and procedures failed to identify the number, type, and frequency of quality control material for Bacitracin A disks and serum hCG tests. 3. An interview on June 28, 2018, at 10:30 AM, with the laboratory lead, confirmed the laboratory failed to monitor the quality control activities for the analytic test systems.
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 records review and an interview with the laboratory lead, the laboratory

	director failed to ensure the quality assessment program for the Cell-Dyn Emerald complete blood count (CBC) test system meets the CLIA requirements since the last survey on September 28, 2016. Refer to D5463, D5481, D5783, D5785. Findings: 1. A record review revealed the laboratory director failed to identify and correct problems in the analytic system. 2. An interview on June 28, 2018, at 10:30 AM, with the laboratory lead, confirmed the laboratory failed to identify, document, and correct problems in analytic system for the CBC testing on the Cell-Dyn analyzer.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a record review of personnel competency assessments and an interview with the laboratory lead, the technical consultant failed to evaluate the competency for 8 out of 8 testing personnel performing complete blood counts (CBC), microscopic examintions for urine and potassium hydroxide (KOH), serum human chorionic gonadotroin (hCG), and post-vasectomy semen analysis for 2017. Findings: 1. A review of personnel documents revealed the technical consultant failed to evaluate the competency for 2 physicians, 2 mid-level practitioners, and 4 nursing assistants performing KOH exams, CBCs, serum hCG and microscopic exams, and post-vasectomy semen analysis since the last survey. 2. An interview on June 28, 2018 at 9: 00 AM, with the laboratory lead, confirmed the technical consultant failed to assess and document the competency for the practitioners and testing personnel.