Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0685441	(X3) Date Survey Completed 09/04/2019
Name of Provider or Supplier U Of L Physicians Primary Care Associates	**Street Address, City, State** 1900 Bluegrass Avenue, Suite 300, Louisville, KY	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on staff interview and record review on September 4, 2019, the Laboratory Director failed to ensure the laboratory was enrolled in proficiency testing for the Speciality of Hematology from January 1, 2019 through August 15, 2019. Findings include: 1. Record review revealed the laboratory failed to participated in the first (1st), and second (2nd) hematology event with the American Proficiency Institute. 2. Interview with laboratory staff, on 09/04/19 at 11:35 AM, revealed the laboratory was not enrolled in proficiency testing from January 1, 2019 through August 15, 2019 and failed to have a system in place to ensure the laboratory was enrolled in proficiency testing.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on staff interview and record review, on September 4, 2019, the Laboratory Director failed to perform and document Annual Competency using the six (6) mandated competency assessment requirements for testing personal. Competency Assessment was not performed using six (6) methods of assessment for two (2) out of two (2) sampled employees from August 12, 2017 through September 3, 2019. Findings include: 1. Record review on September 4, 2019, revealed there was no documented evidence Competency Assessments were performed between August 12, 2019 and September 3, 2019, for two (2) employees that included the following: direct observation of routine patient test performance, direct observation of performance of instrument maintenance function checks and calibration, monitoring the recording and reporting of test results, review of worksheets, review of quality control records, review of proficiency test results, review of maintenance records, assessment of testing external proficiency, testing samples and problem solving skills. 2. Interview with laboratory staff, on September 4, 2019 at 11:30 AM, revealed the facility failed to have a system in place between August 12, 2017 and September 3, 2019 to ensure competency was performed using all six (6) mandated competency assessment requirements.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on staff interview and record review on September 4, 2019, the laboratory scored a zero percent (0 %) for two (2) out of two (2) events in 2018 for the urine microscopy. Findings include: 1. Record review for the second (2nd) and third (3rd) event of 2018 events, revealed the laboratory scored a zero percent (0%) for the presence or absence of CLUE cells. 2. The testing personnel revealed in an interview on September 4, 2019 at 11:30 AM, "they did not feel comfortable performing the test". The testing personnel failed to answer basic questions about performing the microscopic exam.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on staff interview and record review on September 4, 2019, the laboratory director failed to enroll in proficiency testing (See D 6015). The Laboratory Director failed to ensure testing personnel were trained prior to patient testing (See D 6029).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on staff interview and record review, on September 4, 2019, the Laboratory Director failed to ensure Proficiency Testing was ordered for the 2019 testing event. Findings include: 1. Record review revealed no documented evidence proficiency testing was ordered for the Speciality of Hematology from January 1, 2019 through August 15, 2019. 2. Interview with staff, on September 4, 2019 at 11:35 AM, revealed the laboratory had not performed Proficiency testing in the Speciality of Hematology from January 1, 2019 through Sept 4, 2019.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on staff interview and record review, on September 4, 2019, the Laboratory Director failed to ensure appropriate training for staff performing microscopic exam before testing began. Findings include: 1. Review of proficiency testing results for second (2nd) and third (3rd) testing event in 2018 revealed CLUE cells were missed. 2. Review of proficiency results for the first event of 2018, revealed the laboratory missed the microscopic exam for white blood cells. 3. There was no documentation of training for microscopic exam using the six (6) methods of assessment for two (2) of two (2) testing personnel on the CMS-209 form. 4. Testing staff acknowledged in an interview, on September 4, 2019 at 11:30 AM, they were uncomfortable with performing microscopic exams on urine sediment and vaginal secretions.