

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0311465	(X3) Date Survey Completed 02/13/2018
Name of Provider or Supplier Kingston Family Practice Pc	Street Address, City, State 820 West Race Street, Kingston, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: _____ Based on review of Laboratory's Proficiency Testing (PT) records for 2016 and 2017, lack of director and testing personnel signatures on attestation statements and interview with Laboratory Technician, determined the laboratory failed to sign PT attestation statements for the two year period. The findings include: 1. Review of the 2016 and 2017 PT records. 2. Lack of director signature on attestation statements for 2016 and 2017. 3. Lack of personnel signatures on event B of 2017. 4. Interview with Laboratory Technician at approximately 12:00 p.m. February 13, 2018 confirmed that PT attestation statements had not been signed by laboratory director for 2016 and 2017 and for event B of 2017 by the testing personnel. _____</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p>

This STANDARD is not met as evidenced by:

_____ Based on review of 2 CBC (complete blood count) reports, lack of testing persons identification and interview with the Laboratory Technician, determined the laboratory failed to include identity of testing persons on CBC reports reviewed for April 2017 and January 2018. The findings include: 1. Review of 2 CBC reports, one for April 10, 2017 and one for January 25, 2018. 2. Lack of testing persons identification for 2 of 2 reports reviewed. 3. Interview with Laboratory Technician at approximately 12:00 p.m. February 13, 2018 confirmed the CBC reports reviewed did not contain testing persons identification.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

_____ Based on review of unsatisfactory scores for Proficiency Testing (PT) results for event A of 2017 for RBC, HGB and HCT with no corrective action documented and interview with Laboratory Technician, determined the laboratory director failed to have a corrective action plan in place when PT results are unsatisfactory or unacceptable. The findings include: 1. Review of unsatisfactory scores for event A of 2017 for RBC (red blood cell count), HGB (hemoglobin) and HCT (hematocrit) with no corrective action documented. 2. Interview with the Laboratory Technician at approximately 12:00 p.m. February 13, 2018 confirmed there was no corrective action plan in place when PT results are unsatisfactory or unacceptable. _____

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 review of the Laboratory's Quality Assessment (QA) Plan, lack of Quality Control review by director, lack of Personnel Competencies for 2016 and 2017 and upon interview with the Laboratory Technician, determined the Laboratory Director did not ensure quality of laboratory services was maintained for the two year period per QA plan. The findings include: 1. A review of the QA Plan included: a. Assure that accurate and reliable test results are obtained and reported (QC review); b. Assure that lab personnel are adequately

trained and performance is periodically evaluated. 2. There was no documentation of Director review for CBC (complete blood count's) Quality Controls for 2016 or 2017. 3. There was no documentation for semi-annual or annual competency reviews for personnel for 2016 and 2017. 4. Upon interview at approximately 12:00 p.m. February 13, 2018 with the Laboratory Technician, confirmed there was no director review for CBC quality controls or personnel competency reviews to ensure compliance with the QA Plan for the two year period. _____

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

_____ Based on review of employee files which lacked semi-annual evaluations for new hires and upon interview with the Laboratory Technician, determined the Technical Consultant failed to perform and document semi-annual competency evaluations for 2 of 4 testing personnel hired in 2016 and 2017. The findings include: 1. Review of employee file for testing person one hired 6/19/16 lacked semi-annual competency evaluation for performing CBC testing. 2. Review of employee file for testing person four hired 2/20/17 lacked semi-annual competency evaluation for performing CBC testing. 3. Interview with Laboratory Technician at approximately 12:00 p.m. February 13, 2018 confirmed the Technical Consultant failed to perform and document semi-annual competency evaluations for 2 of 4 new testing persons hired during the 2 year period.

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 review of employee files for 2016 and 2017 which lacked annual evaluations for 2 testing personnel and upon interview with the Laboratory Technician, determined the Technical Consultant failed to perform and document annual competency evaluations for 2 of 4 testing personnel. The findings include: 1. Review of employee file for testing person # 1 hired 6/19/16 lacked an annual competency evaluation for 2017 for performing CBC testing. 2. Review of employee file for testing person #3 lacked annual competency evaluations for performing CBC testing for 2016 and 2017. 3. Interview with Laboratory Technician at approximately 12:00 p.m. February 13, 2018 confirmed the Technical Consultant failed to perform and document annual competency evaluations for 2 of 4 testing persons for the 2 year period. _____