Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0193237	10/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Commonwealth Hlth Physician Network	423 3rd Ave, Ste B, Kingston, PA	

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
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 review of laboratory procedure manuals and interview with Office manager, the laboratory failed to establish a complete procedure to assess the competency of 5 of 5 testing personnel (TP) performing Microscopic urinalysis examinations, 3 of 4 TP performing Microscopic Histology examinations and 4 of 4 clinical consultant competency in 2018 and 2019. Findings include: 1. On the day of survey, 10/30/2019, the laboratory failed to provide a complete written policy to assess the competency of 5 of 5 testing personnel (TP) performing Microscopic urinalysis examinations, 3 of 4 TP performing Microscopic Histology examinations and 4 of 4 clinical consultant competency in 2018 and 2019. 2. The office manager could not provide competency assessments records for 5 of 5 TP performing Microscopic urinalysis examinations, 3 of 4 TP performing Microscopic Histology examinations and 4 of 4 clinical consultant competency in 2018 and 2019. 3. 6029 Microscopic urinalysis examinations were performed in 2018. 4. 73 Microscopic Histology examinations were performed in 2018. 5. The office manager confirmed the findings above on 10/30/2019 around 10: 15 am. **** Repeat Deficiency****
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 review of records and interview with the office manager, the laboratory failed to perform at least twice annually, accuracy verification of microscopic urinalysis examinations performed in 2018. Findings Include: 1. The CMS 2567 plan of correction form signed by the previous director on 11/30/2017 states " The office manager will ensure that this deficient practice does not recur by overseeing all clinical personnel". 2. On the day of survey, 10/30/2019, the office manager could not provide documentation of accuracy verification perform at least twice annually for Microscopic Urinalysis in 2018. 3. 6,029 Microscopic Urinalysis examination were analyzed in 2018. 4. The office manager confirmed the findings above on 10/30/2019 around 9:23 am. **** Repeat Deficiency****
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with the office manager and laboratory director (LD), the laboratory failed to have a written procedure for histopathology slide examinations available to all laboratory personnel from 2018 to the date of survey. Findings Include: 1. On the date of survey, 10/30/2019, the office manager and LD could not provide a procedure for histopathology slide examinations read onsite from January 2018 to October of 2019. 2. The office manager confirmed the finding above on 10/30/2019 around
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation and interview with the office manager, the laboratory failed to ensure procedures were approved, signed, and dated by the current laboratory director before use from 10/01/2018 to the date of survey. Findings Include: 1. On the day of survey, 10/30/2019, observation and review of procedure manuals revealed, the current LD (Hired 10/01/2018), did not approve, sign, and date laboratory procedures before use from 10/01/2018 to the date of survey. 2. On 10/30/2019, the office manager confirmed that procedure manual reviewed did not have the current director's signature and date of approval around 9:45 am.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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--

	At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control records, and interview with the office manager, the laboratory failed to perform quality control (QC) each day of patient testing for Microscopic Urinalysis examinations from 2017 to the date of survey. Findings Include: 1. The CMS 2567 plan of correction form signed by the previous director on 11/30/2017 states " The office manager will ensure that this deficient practice does not recur by overseeing all clinical personnel". 2. On the date of survey, 10/30/2019, the laboratory could not provide QC documentation for Microscopic Urinalysis examinations performed each day of patient testing from December 2017 to October 2019. 3. 6029 Microscopic Urinalysis examination were analyzed in 2018. 4. The office manager confirmed the finding above on 10/30/2019 around 9:50 am. **** Repeat Deficiency****
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with the office manager, the laboratory director failed to ensure quality assessment programs were maintained and documented to assure the quality of laboratory services for urine microscopic examinations and histopathology slide examinations from December 2017 to the day of survey. Findings Include: 1. On the day of survey, 10/30/2019, review of the laboratory's manuals revealed that the laboratory failed to follow their policy on how to assess the quality of urine microscopic examinations and histopathology slide examinations test systems from December 2017 to September 2019. 2. The last laboratory's quality assessment of its pre-analytic, analytic and post analytic phases of testing was performed on November of 2017. 3. The office manager confirmed the findings above on 10/30/2019 around 9:40 am.