Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0120264	(X3) Date Survey Completed 09/05/2019
Name of Provider or Supplier Cape May County Department Of Health	**Street Address, City, State** 6 Moore Road, Cape May Court House, NJ	

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 surveyor review of the procedure manual (PM) and Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to follow its policies and procedures for assessing the competency of the TP in the calendar years 2018 and 2019. The findings include: 1. The laboratory failed to follow the PM and did not evaluate these elements: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring the recording and reporting of test results. c. Direct observation of performance of instrument maintenance and function checks. d. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. e. Evaluation of problem-solving skills. 2. There was no documentation competency was met for procedures evaluated on the CA form. 3. The TP #1 confirmed on 9/5/19 at 11: 00 am that CA procedures were not followed.
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 lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 9/26/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed 9/5/19 at 12:00 pm that a QA plan had not been established.