Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0701535	(X3) Date Survey Completed 09/10/2020
Name of Provider or Supplier District Health Center 1	**Street Address, City, State** 1930 South Broad Street, 2nd Floor, Unit #30, Philadelphia, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the Quality Assessment Officer (QAO), the Laboratory Director (LD) failed to sign 10 of 10 PT attestation statements reviewed from 2018 to 2020. Findings include: 1. The API Attestation Statement Signature page states, "Testing personnel and the laboratory director (or designee) must physically sign an attestation statement for all PT results" 2. On the day of survey, 09/10/2020, review of API PT records revealed, the following API PT attestation statement documents were not signed by the LD: - 2018: Event #3, Hematology/coagulation. Event #3, Microbiology. - 2019: Event#1, Event#2, Event #3: Hematology/coagulation Event#1, Event#2, Event #3: Microbiology - 2020: Event #1: Hematology/coagulation Event #1: Microbiology 3. During an interview on 09/10/2020 at 12:20 p.m. the Quality Assessment Officer stated the laboratory director had a saved electronic signature with API for the attestation statement. 4. The API Quality and Compliance manager was contacted on 9/17/2020, she stated that the laboratory director/designee must physically signed the attestation statement and keep the records on site.
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:
A. Based on review of the laboratory's Administrative Policy and Procedure Manual Competency Assessment Program, and interview with the Quality Assessment Officer (QAO), the laboratory failed to have a competency assessment (CA) policy for the 1 of 2 Clinical Consultant, and 1 of 1 Technical Consultant (on the CMS 209 form, listed as personnel #2 and #3) for their supervisory responsibilities from 2018 to the date of survey. Findings include: 1. On the day of survey, 09/10/2020, the QAO could not provide a CA policy to assess the competency of 1 of 2 CC (personnel #2) and 1 of 1 TC (personnel #3) for their supervisory responsibilities in 2018,2019, and 2020 2. The Quality Assessment Officer confirmed the finding above on 09/10/2020 around 10:30 am. B. Based on review of the laboratory's Administrative Policy and Procedure Manual Competency Assessment Program, record review, and interview with the Quality Assessment Officer (QAO), the Laboratory failed to follow the Laboratory's written policies and procedures to assess the competency of 3 of 3 testing personnel (TP) who performed gram stains and rapid plasma reagin (RPR) from 01/01/2019 to 12/31/2019. Findings Include: 1. The laboratory's Administrative Policy and Procedure Manual Competency Assessment Program (page 2) under methods for evaluating competency (points 1, 2, 3, 4, 5, and 6) states: " 1. Direct observation of routine patient test performance to include patient preparation (if applicable), specimen handling, processing and testing. 2. Monitoring the recording and reporting of test results. 3. Review of patient test results recorded in the information system /worklists, quality control records, proficiency testing results, and preventative maintenance records. 4. Direct observation of performance of instrument maintenance and function checks and/or test procedure. 5. Assessment of test performance through previously analyzed specimens, internal blind samples or external proficiency testing samples. 6. Assessment of knowledge and problem solving skills through written or verbal examination." 2. On the day of survey 09/10/2020 review of the competency assessment records during 2019 for 3 of 3 TP revealed the laboratory did not follow their Policy to evaluate points 1, 2, 3, and 6 for gram stains and RPR. 3. On 9/10/2020 at 09:45, the Quality Assessment Officer confirmed the findings above. C. Based on review of the laboratory's Administrative Policy and Procedure Manual Competency Assessment Program, record review, and interview with the Quality Assessment Officer (QAO), the Laboratory failed to follow the Laboratory's written policies and procedures to assess competency for 9 of 9 testing personnel (TP) who performed potassium hydroxide (KOH) and wet mounts from in 2018,2019, and 2020. Findings include: 1. The Administrative Policy and Procedure Manual Competency Assessment Program (page 2) under methods for evaluating competency states the six CLIA procedures for competency assessment as shown in point B. 2. On the day of the survey, 9/10/2020 review of the competency assessment records for 9 of 9 TP revealed the laboratory did not follow their policy to evaluate points 1, 2, 3, and 4 for KOH and wet mounts 3. On 09/10/202 at 10:12 a.m. the QAO confirmed the findings above. D. Based on review of competency assessment records, and interview with the Quality Assessment Officer (QAO), the Laboratory failed to asses the competency for 3 of 9 testing personnel (TP) (on the CMS-209 form listed as personnel 8, 12, and 13) who performed potassium hydroxide (KOH) and wet mounts from 01/01/2019 to 12 /31/2019. Findings include: 1. On the day of survey, 09/10/2020, the Quality Assessment Officer could not provide competency assessment records for TP 8, 12 and 13 who performed KOH and wet mount in 2019. 2. The QAO confirmed the finding above on 09/10/2020 around 10:15 am

D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure, proficiency testing records, interview with Technical Consultant (TC) and Laboratory Director (LD), the LD failed to ensure that 1 of 1 2019 American Proficiency Institute (API) unsatisfactory proficiency test report was reviewed and a corrective action taken to identify the problem. Findings include: 1. Proficiency testing program policy ADM-13.02 version Oct 11 2018 states that " LD is responsible for oversight of the proficiency program. Review and documentation of all participant summary evaluation and corrective actions". 2. A review of API proficiency test records revealed a score of 0% for vaginal wet prep 1st event of 2019. 3. On the date of survey the laboratory could not provide documentation of review and corrective action taken for API 2019 vaginal wet prep 1st event. 4. On 9/10/2020 at 10:30 am, the TC confirmed the above findings.