Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0886072	(X3) Date Survey Completed 05/09/2018
Name of Provider or Supplier Cdph/Mccafferty Health Center	Street Address, City, State 4242 Lorain Avenue, Cleveland, OH	

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 record review and interviews with the Laboratory Director and testing personnel (TP) #2, the Laboratory Director failed to attest to the routine integration of the American Association of Bioanalysts (AAB) proficiency testing (PT) samples into the routine patient workload using the laboratory's routine methods for seven of 10 of the testing events. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any PT policies and procedures. 2. Review of seven out of 10 of the laboratory's 2016, 2017 and 2018 AAB PT records revealed Technical Consultant (TC) #2 attested as the Laboratory Director to the routine integration of the AAB PT samples into the patient workload using the laboratory's routine methods for the third Chemistry and non-Chemistry PT events in 2016, the first and second Chemistry and non-Chemistry and the third non-Chemistry PT events in 2017 and did not find that the Laboratory Director provided their attestation. 3. Review of a delegation letter from the previous Laboratory Director, signed and dated on 09/21/2016, did not include the delegation of PT attestation as the Laboratory Director, however revealed the following PT delegation statement: "...I hereby do give responsibility to qualified technical supervisor, 'name of TC#3', to review proficiency tests..." 4. The Laboratory Director and TP#2 confirmed the letter did not include the delegation of PT attestation as the Laboratory Director and the Laboratory Director did not provide PT attestation for seven out of 10 PT events in 2016 and 2017, as required. The interviews occurred on 05/09/2018 at 2:45 PM.

D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and testing personnel (TP) #2, the laboratory failed to document the handling, preparation, processing, examination and each step in the testing and reporting of proficiency testing (PT) results. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any mention of PT policies and procedures. 2. The Surveyor requested the laboratory's PT policy and procedure from the Laboratory Director and TP#2. The Laboratory Director and TP#2 confirmed the laboratory did not have an established PT policy and procedure. The interviews occurred on 05/09/2018 at 2:45 PM.
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 record review and interviews with the Laboratory Director and testing personnel (TP) #2, the Technical Consultant (TC) failed to evaluate and document the competency of three out of three of the TP responsible for moderate complexity Microbiology, Immunology and Chemistry testing procedures at least annually after the first year. Findings Include: 1. Review of the laboratory's "Competency and Training" manual and the "Assessing Testing Personnel Competency" policy and procedure, approved by the Laboratory Director on 12/18/2017 and provided on the date of the inspection, found instructions to assess the competency of testing personnel annually after the first year of testing patient samples. 2. Review of the laboratory's 2016 and 2017 annual competency assessment records for TP#1, TP#2 and TP#3 for the moderately complex gram stain, potassium hydroxide (KOH), wet mount preparation, rapid plasma reagin (RPR), urine microscopic and urine drug screen testing procedures performed revealed the competency assessments were actually conducted by TP, who possessed Associate of Applied Science in Medical Technology degrees, were not listed and did not qualify as a TC. 3. The Surveyor requested the laboratory's 2016 and 2017 annual competency assessment records conducted by a qualified TC for TP#1 in 2016 and 2017 and for TP#2 and TP#3 in 2017 from the Laboratory Director and TP#2. The Laboratory Director and TP#2

	confirmed that the above mentioned annual competency assessments for the moderately complex testing procedures were not conducted by a qualified TC at least annually after the first year of testing patient specimens, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 05/09/2018 at 4:40 PM.