

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0336805	(X3) Date Survey Completed 05/09/2018
Name of Provider or Supplier Cdph J Glen Smith Health Center Lab	Street Address, City, State 11100 St Clair Avenue, 2nd Floor, 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	<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 record review and interviews with the Laboratory Director and testing personnel (TP) #1, the Laboratory Director failed to attest to the routine integration of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) samples into the routine patient workload using the laboratory's routine methods for two of three of the testing events in 2017. 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 two out of five of the laboratory's 2016, 2017 and 2018 MLE PT records revealed Technical Consultant (TC) #3 attested as the Laboratory Director to the routine integration of the MLE PT samples into the patient workload using the laboratory's routine methods for the first and third PT event 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 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#1 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 the first and third PT event of 2017, as required. The interviews occurred on 05/09/2018 at 11:30 AM.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p>

(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) #1, 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#1. The Laboratory Director and TP#1 confirmed the laboratory did not have an established PT policy and procedure. The interviews occurred on 05/09/2018 at 11:50 AM.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Laboratory Director and testing personnel (TP) #1, the laboratory failed to retain the proficiency testing (PT) attestation record for the third PT event of 2016. 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 one out of five of the laboratory's 2016, 2017 and 2018 MLE PT records did not find the laboratory's PT attestation page for the third PT event of 2016. 3. The Surveyor requested the laboratory's 2016 PT attestation documentation for the third PT event of 2016 from the Laboratory Director and TP#1. The Laboratory Director and TP#1 confirmed the laboratory could not locate the requested PT attestation documentation and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 05/09/2018 at 11:30 AM.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the

type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Laboratory Director and testing personnel (TP) #1, the Laboratory Director failed to ensure that prior to testing patients' specimens, TP#3, who was responsible for moderately complex testing procedures, had documentation of training and that they had demonstrated that they could perform urine microscopic, wet mount preparation, potassium hydroxide (KOH), gram stain and rapid plasma reagin (RPR) testing reliably to provide and report accurate results. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 04/27/2018 and provided on the date of the inspection, revealed one out of three individuals newly listed as TP, since the last CLIA inspection on 08/25/2016, to perform moderately complex testing procedures. 2. Review of the laboratory's 2017 competency assessment documentation, provided on the date of the inspection, did not find that TP#3 had training and assessment documentation prior to testing patients' specimens independently on 07/31/2017. 3. The Surveyor requested the laboratory's 2017 training and assessment documentation prior to testing patients' specimens for TP#3 from the Laboratory Director and TP#1. The Laboratory Director and TP#1 confirmed the laboratory did not have training and assessment documentation prior to testing patients' specimens independently on 07/31/2017 for TP#3 and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 05/09/2018 at 11:29 AM.