

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0691828	(X3) Date Survey Completed 08/13/2019
Name of Provider or Supplier Illinois Department Of Public Health -Chicago	Street Address, City, State 2121 W Taylor St, Chicago, IL	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to meet proficiency testing requirements by engaging in interlaboratory communication prior to the proficiency testing submission deadline with two laboratories for one proficiency testing event in 2019. (See D2011)</p>
D2011	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)</p> <p>Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.</p>

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory engaged in communication across site locations regarding the Laboratory Response Network (LRN) Proficiency testing (PT) event of June 2019. Staff from three different locations had several discussions about the June 2019 PT event prior to the submission deadline date. Findings include: 1. The procedure titled "Standard Operating Procedure for Handling, Analysis and Reporting of Proficiency Testing Samples" under section 5 "Interlaboratory Consultations" stated "5.1 The IDPH laboratories are strongly encouraged to consult with one another and provide technical expertise when there are problems with procedures or particular patient samples. However, great care must be taken to avoid even the appearance of consulting on issues specifically involving PT samples. If an issue involves only PT samples no consultation/communication may be done. If there is an issue requiring consultation which also involves patient samples the consultation should be done but there should be no specific reference to the PT samples. 5.2 When an issue involving only PT samples requires a consultation in order to report results, report as "would refer" or equivalent, if possible. 5.3 Consultations regarding issues specifically pertaining to PT samples may be made only after the samples have been graded/evaluated by the PT agency and the results of the evaluation have been received by IDPH laboratory." 2. Review of "LRN Proficiency Testing Instructions for Analysis and Results Reporting" revealed under "Testing Instructions" that "Laboratories must report their test results or referral of the samples within 3 business days of package receipt." 3. Review of the document Appendix 7.1 titled "Illinois Department of Public Health - Division of Laboratories Commercially Prepared or CMS approved Proficiency Testing Performance Report" indicated the LRN Pox virus PT arrived June 25, 2018 at 10:30 A.M. and results were submitted June 28, 2019. 4. Review of an email sent to testing personnel #1 (TP#1) revealed that on June 14, 2019 an invite for June 25, 2019 from 14:30 - 15:00 with "Subject: LRN Orthopox PT Discussion" was sent to laboratory personnel at the following three laboratories: CLIA #14D0691828, #14D0647002, and #14D0647032. 5. Interview with TP#1 on August 13, 2019 at approximately 10:00 A.M. revealed that on June 25, 2019, a teleconference took place with staff from all three laboratories and discussions regarding the risk level and what testing should be performed on the proficiency testing took place. 6. Review of an email sent to TP#1 revealed that on June 26, 2019 testing personnel from CLIA #14D0647002 sent a summary of the June 25, 2019 meeting to laboratory personnel at both #14D0691828 and #14D0647032. The summary included the Sample ID (PT06191 - PT06195) and the Recommended Action (risk level and testing to be performed). 7. Review of emails sent to TP#1 on June 26, 2019 and June 27, 2019 revealed additional discussion of the risk assessment of proficiency testing sample PT06194 by all three laboratories. 8. Review of an email sent by testing personnel from CLIA# 14D0647002 on June 27, 2019 to TP#1 and a testing personnel at CLIA# 14D0647032 had an attachment with the rash algorithm risk assessment submitted to Centers of Disease Control for CLIA# 14D0647002. 9. Interview with the laboratory director on August 13, 2019 at approximately 2:15 P.M. confirmed that all three laboratories discussed the risk level and testing to be performed for the LRN Proficiency testing June 2019 PT samples.

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 record review and interview, the laboratory failed to follow their procedure requirement to assess testing personnel at six months during the first year the individual tests patient specimens in five out of five testing personnel (TP) reviewed. Findings: 1. The laboratory procedure DCA001-19-1018 states in section 2.6 "Personnel Competency and Proficiency Assessment" the following "Assessment and documentation of the performance of individuals responsible for testing must be done initially upon completion of training and at six months during the first year the individual tests patient specimens." 2. Review of competency records revealed the following: a. TP#2 for "NBS by GSP for CAH, TSH, t4, IRT, TGAL, and GALT" initial assessment was 10/19/18. Six-month assessment was performed 06/06/19. b. TP#3 for "NBS by GSP for CAH, TSH, t4, IRT, TGAL, and GALT" initial assessment was 2/12/18. Six-month assessment was performed 07/24/19. c. TP#4 for "NBS by GSP for CAH, TSH, t4, IRT, TGAL, and GALT" initial assessment was 10/19/18. Six-month assessment was performed 06/21/19. d. TP #5 for "NBS by GSP for CAH, TSH, t4, IRT, TGAL, and GALT" initial assessment was 10/19/18. Six-month assessment was performed 06/12/19. e. TP#6 for "Isolation and ID of Yersinia and Vibrio/biochemical/serotyping/microscope/DCM0003" initial assessment was 10/1/18. Six-month assessment was performed 06/17/19. 3. During interview on August 12, 2019 at approximately 12:45 PM, TP#7 confirmed that the laboratory did not follow procedure and perform competency at six months during the first year.