Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0647002	08/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Illinois Department Of Public Health- Springfield	825 N Rutledge St, Springfield, 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	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. 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)
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) 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.

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 laboratory's 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. The laboratory's packing slip for the LRN Proficiency Testing Samples for Pox Viruses was stamped June 25, 2019 10:59 AM. 4. Review of an email appointment sent by TP#1 revealed a teleconference to discuss the LRN Orthopox PT was set for June 25, 2019 with required attendees from three laboratories (14D0691828, 14D0647002, 14D0647032) including the laboratory director and clinical consultant. The laboratory director and clinical consultant are the same for all three laboratories. 5. Interview with TP#1 on August 14, 2019 at 1410 confirmed that the teleconference took place and there was a discussion regarding the LRN Orthopox PT with staff from all three laboratories present. 6. Review of an email sent on June 26, 2019 by TP#2 to staff from all three laboratories stated "So as a brief summary to yesterday's meeting, here's what we're going to essentially do for each sample. Please correct me if I'm wrong." The email then listed a chart of the Sample ID (PT06191 - PT06195) and the Recommended Action (risk level and testing to be performed). 7. Review of an email sent on June 27, 2019 by the laboratory director to staff from all three laboratories revealed the following statement "What I need from you and is for you to complete the details for the outcome of the collaboration. That can be shared because we collaborated and came to decisions on each of the cases. TP#2 did a summary of recommended actions (testing to perform. For each PT sample, I need you to provide this group with the remaining info that was the outcome of the collaboration that is require for entry in the report." 8. Review of an email sent by TP#2 on June 27, 2019 to testing personnel at CLIA# 14D0647032 and 14D0647032 revealed an attachment with the rash algorithm risk assessment submitted to Centers of Disease Control for CLIA# 14D0647002. 9. Interview with TP#2 on August 14, 2019 at 3:15 P.M. confirmed that the attachment contained the risk criteria and what testing should be performed on each proficiency testing sample.