Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0662599	05/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Indiana State Department Of Health Laboratories	550 W 16th St, Indianapolis, IN	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to ensure expired rubella wash reagent was not available for use for one of one patients with rubella testing reviewed. Findings include: 1. Observation on 05/15/18 at approximately 10:30 AM, showed rubella wash reagent in the refrigerator available for use with the expiration date of 07/01/2017. 2. Review of results, for one of one patients with rubella testing reviewed, revealed rubella testing was performed on 05/11 /18. 3. During interview on 05/15/18 at approximately 10:30 AM, general supervisor (GS) #1 confirmed the rubella wash reagent was expired and patient testing was performed after the expiration date. 4. During interview on 05/15/18 at approximately 10:45 AM, GS#1 stated that the expired rubella wash reagent was not used for patient testing performed on 05/11/18.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on record review and interview, the laboratory failed to follow the manufacturer's specification for quality control for optochin, Neisseria meningitidis serotyping, and Haemophilus influenzae serotyping testing for one of one patients reviewed for each of the tests. Findings include: Optochin testing 1. Review of "Streptococcus pneumoniae Testing Worksheet", for one of one patients reviewed, revealed optochin testing was set up on 03/14/18 and read on 03/15/18. 2. Review of the manufacturer's package insert for "BD BBL Taxo P Discs for Differentiation of Pneumococci" under "User Quality Control" revealed "At time of use, check performance with pure cultures of stable control organisms producing known desired reactions." 3. Review of the optochin disk quality control log revealed no documentation of quality control performance on either 03/14/18 or 03/15/18. 4. During interview on 05/17/18 between approximately 10:30 and 11:30 AM, technical supervisor (TS) #1 and general supervisor (GS) #2 confirmed that optochin quality control was not performed at time of use per manufacturer's specifications but with each new lot, shipment, and at least once every six months thereafter. Neisseria meningitidis serotyping 1. Review of "Neisseria meningitidis Testing Worksheet", for one of one patients reviewed, revealed serotyping was performed on 05/03/18. 2. Review of the manufacturer's package insert for "BD Difco Neisseria Meningitidis Antisera" under "User Quality Control" revealed "At time of use, test both positive and negative control cultures to check performance of the antisera, techniques and methodology." 3. Review of the Neisseria meningitidis antisera group A, B, C, Y and W135 quality control logs revealed no documentation of quality control performance on 05/03/18. 4. During interview on 05/17/18 between approximately 10:30 and 11:30 AM, TS#1 and GS#2 confirmed that Neisseria meningitidis serotyping quality control was not performed at time of use per manufacturer's specifications but with each new lot, shipment, and at least once every six months thereafter. Haemophilus influenzae serotyping 1. Review of "Haemophilus influenzae Testing Worksheet", for one of one patients reviewed, revealed serotyping was performed on 01/31/18. 2. Review of the manufacturer's package insert for "BD Difco Haemophilus Influenzae Antisera" under "User Quality Control" revealed "At time of use, test both positive and negative control cultures to check performance of the antisera, techniques and methodology." 3. Review of the Haemophilus influenzae antisera group a, b, c, d, e, and f quality control logs revealed no documentation of quality control performance on 01/31/18. 4. During interview on 05/17/18 between approximately 10:30 and 11:30 AM, TS#1 and GS#2 confirmed that Haemophilus influenzae serotyping quality control was not performed at time of use per manufacturer's specifications but with each new lot, shipment, and at least once every six months thereafter.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, one (testing personnel #8) out of sixteen testing personnel reviewed failed to meet qualifications of high complexity testing personnel. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

	This STANDARD is not met as evidenced by: Based on record review and interview, one (testing personnel #8) out of sixteen testing personnel reviewed did not meet the qualifications to perform high complexity testing. Findings include: 1. Review of testing personnel (TP) #8 education credentials showed that the documentation was from a foreign (non-US) education institution and there was no foreign equivalency documentation available to show how TP#8 met the CLIA education requirements for high complexity testing. 2. During interview at approximately 1530 on 05/17/18, the quality assurance director confirmed that foreign equivalency documentation was not available for TP#8.