Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0662599	01/21/2021
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on record review and interview, the laboratory failed to follow their procedure for quality control (QC) for four out of ten patients reviewed for optochin and bile solubility testing. 1. Procedure "ISDH-GMICRO_28 Streptococcus pneumonia ID and Serotyping" stated the following under section 12.0 "QC Requirements and Frequency of QC" "QC for Bile Solubility test: A. QC is performed on newly received lot or shipment of reagent with a known positive control organism and sterile saline, which serves as the negative control. B. QC is also performed with each day of testing." and "QC for Optochin (P disc): A. QC is performed on newly received lot, batch, or shipment of discs with known sensitive and resistant control organisms to disc AND QC is performed as frequently as the manufacturer requires." 2. The package insert for BD BBL (Trademark)Taxo (Trademark) P Discs states "User Quality Control: At the time of use, check performance with pure cultures of stable control organisms producing known desired reactions." 3. Review of four of seven patient records (C20000XXX, C2000XXXX, C2000XXXX, and C2000XXXX) revealed optochin and bile solubility were performed on the following dates: 01/14 /2020, 01/28/2020, 01/29/2020, and 02/17/2020. 4. Review of quality control records revealed no quality control recorded for bile solubility and optochin testing on the above dates. 5. The technical supervisor (TS) #1 confirmed that bile solubility and optochin QC were not performed each day of patient testing on 11/30/2020 at approximately 2:00 P.M. B. Based on record review and interview, the laboratory failed to follow their procedure for quality control for one out of one patients

	reviewed for Legionella antisera testing. 1. Procedure "ISDH-GMICRO-48 Legionella Culture for Identification/Confirmation" stated in section "12.0 QC Requirements and Frequency of QC" under "QC for Antiserum (if available):" the following "B. QC is performed on each lot, shipment or batch of reagents with known positive and negative antigen control organisms. In addition, QC is performed at each time of use when patient testing." 2. Review of one of one patient record (20REF00XX) revealed that the specimen was tested with Legionella antisera Group 1 on 06/17/2020. 3. Review of quality control records for Legionella Pneumophilia Antiserum Group-1 revealed no quality control recorded for the above date. The last date of quality control testing was 09/10/2019. 4. The TS#1 confirmed the above findings on 11/30 /2020 at approximately 3:30 P.M. C. Based on record review and interview, the laboratory failed to follow their procedure for setup and culture examination for four of seven patients reviewed for yeast identification and confirmation. 1. Procedure "ISDH-GMICRO-54 Yeast Identification and Confirmation" stated in section "15.2 Setup and Culture Examination of Yeast Isolates" under "A. Initial Setup" the following "1. Label a PDA plate, a SAB plate, and a Columbia SBA plate with the isolate lab number, inoculation date, and the initials of the individual setting up the isolate." and "5. Examine the plates after overnight incubation or at the next available work day". Under section "20.0 Reporting of Results" the procedure states "A. Record observations of the appropriate spots on the lab worksheet, lab book, and electronic lab record." 2. Review of the Mycology Worksheet revealed on page 2 a place to record the media set up, the result, the date read, and the initials of the testing personnel. 3. Review of four of seven patient's (20MYC000X, 20MYC00XX, 20MYC00XX, 20MYC00XX) lab worksheets revealed no documentation of the media used to subbed the specimen, the date the specimen was plated, or the date the media was checked for growth. 4. The TS#1 confirmed the above findings on 12/01 /2020 at approximately 08:50 A.M.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Over time, rotate control material testing among all operators who perform the test. (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 rotate gram stain and catalase quality control among all operators for two of two years reviewed. 1. Review of C200XXXXX Listeria Worksheet revealed gram stain and catalase testing were performed by testing personnel #1 (TP#1) . 2. In interview on January 20, 2021 at approximately 09:15 A.M., TP#1 indicated that reagents from another department were used for gram stain and catalase testing. Quality control for gram stain and catalase testing was performed by staff assigned to a different testing area within the laboratory. 3. Review of the gram stain and catalase quality control logs for 2019 and 2020 revealed that quality control had not been performed by TP #1 for two of two years reviewed. 4. In interview on January 20, 2021 at approximately 09:25 A.M., technical supervisor #2 confirmed that staff does not rotate gram stain and catalase quality control among all operators.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (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 test each batch, lot, and shipment of catalase, oxidase, and/or indole reagents for positive and negative reactivity for two of three patients reviewed in the biological threat (BT) department. 1. Review of two patient (C190XXXXX and C20XXXXXX) records indicated oxidase, catalase, and/or indole testing was performed. 2. Review of BT procedure, LRN-1074 , indicated under the quality control section to "Perform quality control of media and reagents according to package inserts, NCCLS document M22-A2, and CLIA standards, using positive and negative controls appropriate for each media and reagent. Document all quality control results according to standard laboratory practices." 3. Review of BT procedure, LRN-1047, indicated under quality control section "Clinical Laboratory Improvement Amendments (CLIA) policies and guidelines should be enforced when examining human specimens." 4. During interview on January 20, 2021 at approximately 11:20 A.M., technical supervisor #3 indicated that quality control had not been performed or documented for catalase, oxidase, or indole reagents in the BT department.