Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2163536	09/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Indy Health Labs Llc	4118 Franklin Rd Suite A, Roanoke, VA	

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
D0000	An announced CLIA Recertification survey was conducted at the Indy Health Labs LLC on September 20 & 21, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5200 - 42 C.F.R. 493-1230 Condition: General Laboratory Systems.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CMS-209 Form), policy and procedures (P&P), personnel competency assessment records, lack of documentation and interviews, the laboratory failed to establish a competency policy to evaluate personnel that held the supervisory position of technical supervisor (TS) and general supervisor (GS) listed on the CMS-209 Form at the dates of survey on September 20 & 21, 2023. Refer to D5209, repeat deficiency.
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: **REPEAT DEFICIENCY** Based on the review of the Laboratory Personnel Report Form (CMS-209 Form), policy and procedures (P&P), personnel competency assessment records, lack of documentation and interviews, the laboratory failed to establish a policy to evaluate competency of personnel performing the duties of technical supervisor (TS) and general supervisor (GS) listed on the CMS-209 Form at the dates of survey on September 20 & 21, 2023. Findings include: 1. Review of the CMS-209 Form and interview with the lab director and general supervisor on 09/20 /23 at 09:30 AM revealed a new lab director as of 03/01/22 and new GS as of 07/23 /22. The TS was not a new hire since the date of the last survey on 10/08/21. 2. Review of P&P revealed lack of documentation of an established policy for performing competency assessments of personnel designated for the role of TS and GS. The inspector requested to review the specified policy. The policy was not available at the dates of survey. 3. An exit interview with the lab director and GS on 09/21/23 at 11:30 AM confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of chemistry analyzer calibration records, lack of documentation and interview, the lab failed to perform calibration verification studies every six months for the creatinine analyte for 15 months from 10/21/21 up to 12/31/22. Findings include: 1. Review of the Beckman Coulter AU480 calibration records for the creatinine analyte revealed a two-point calibration. 2. Review of available calibration verification records revealed that the lab performed linearity studies using Maine Standards on 01/17/23 and 06/23/23. The record review lacked documentation of calibration verification studies performed since the date of last survey on 10/08/21 up to 01/17/23. The inspector requested to review additional calibration verification

	documents. No documentation was available for review. 3. An exit interview with the lab director and GS on 09/21/23 at 11:30 AM confirmed the findings.