Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2163536	10/08/2021
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 October 8, 2021 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:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the review of available maintenance records, lack of documentation, manufacturer's user guide and interviews, the lab failed to retain documentation of the performance of daily and weekly maintenance for the chemistry analyzer from 03/10 /20 up to 05/21/21 (15 months and 10 days). Findings include: 1. Review of the available maintenance records revealed lack of documentation of the performance of the required daily and weekly maintenance procedures for the Beckman Coulter AU480 chemistry analyzer from 03/10/20 up to 05/12/21. An interview with the primary testing personnel on 10/08/21 at approximately 12:20 PM revealed that the lab utilizes the stored history of the performance of maintenance records as documentation of performance for the Beckman Coulter AU480 chemistry analyzer (serial number 503415). The lab does not print the records on a regular basis. The inspector reviewed the printed history records from 08/10/21. The printed history lacked recordings of maintenance procedures prior to 05/21/21. The inspector requested documentation of the daily and weekly maintenance procedures from 03/10 /20 up to 05/12/21. The documentation could not be retrieved from the analyzer. 2. Review of the manufacturer's user guide (Chapter 8- Maintenance) revealed the following maintenance procedures, to include but not limited to: Daily- inspect

	sample syringe for leaks, inspect reagent syringe for leaks, and insect and clean sample probe, reagent probe and mix bars. Weekly- Perform wash 2, perform photocal, manual wash of sample probe, and clean sample pre-diluent bottle. 3. An exit interview with the primary testing personnel, general supervisor and lab owner on 10/08/21 at approximately 4:00 PM confirmed the findings.
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 the review of policy and procedures (P&P), lack of documentation, and interview, the laboratory did not have a P&P for performing competency assessments on individuals performing the job duties of technical supervisor (TS), general supervisor (GS) and technical consultant (TC) at the date of the survey on 10/08/21. Findings include: 1. Review of the available P&P's revealed lack of documentation of a policy for performing competency assessments on individuals performing the job duties of TS, GS and TC. The inspector requested to review the P&P for competency assessments. The document was not available for review at the date of survey. 2. An exit interview with owner of the lab and the primary testing personnel on 10/08/21 at approximately 3:00 PM confirmed the findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), lab test menu, proficiency testing records (PT), and interviews, the laboratory failed to perform twice annual accuracy verifications for 44 of 44 urine toxicology analytes from July 2020 up to the date of survey on 10/08/21 (14 months). Findings include: 1. Review of the P&P revealed the following, "SOP for Proficiency Testing (PT)" (signed by the lab director 02/01/20), "For "unregulated" testing (tests for which PT is not required), and/or testing for which Proficiency Test Specimens are not available, CUA requires laboratories to take steps to assure the accuracy of testing in lieu of testing PT samples. CLIA requires that, at least twice annually, the accuracy of any test or procedure that is performed and is not listed in Subpart I, be verified for accuracy." 2. Review of the lab test menu revealed the lab performs toxicology screening via AB Sciex 4500 Triple Quad Liquid Chromatography (LC) - mass spectrometer (MS) analyzer for the following analytes: 6-MonoAcetlymorphine, 7-Aminoclonazepam, alpha-Hydroxyalprazolam, Amphetamine, Alprozolam, Benzoylecgonine, Buprenorphine, Butalbital, Carisoprodol, Clonazepam, Codeine, Clycobenzaprine, Diazepam, dihydrocodeine, Ethyl-Sulfate, EDDP, Fentanyl, flunitrazepam, Gabpentin, Hydrocodone, Hydromorphone, Lorazapam, MDMA, Methamphetamine, Methadone, Meprobamate, Meperidine, Morphine, Naloxine, Norbuprenorphine, Nordiazepam, Norfentanyl, Norhydrocodone, Noroxycodone, O-desmethyltramadol,

	Oxycodone, Oxymorphone, Oxaepam, PCP, Pregabalin, Tapentadol, Temazepam, THCA, Tramadol, and Zolpidem. Total of 44. 3. Review of the available PT documents from the College of American Pathology (CAP) DMPM-A and B events and interview with the general supervisor and lab owner on 10/07/21 at approximately 10:30 AM revealed the lab received, tested and faxed results on 03/31/21 (Event A) and 08/31/21 (Event B). The original evaluations from CAP provided the code "[40] Results for this test kit were not received" for both events. The CAP DMPM-A 2021 revised evaluation on 10/08/21 revealed the unacceptable results for Hydromorphone, nordiazepam, morphine and pregabalin. No revision evaluation was available for CAP DMPM-B 2021 at the date of survey. At the date of survey, neither events and evaluations had been reviewed by the general supervisor, technical supervisor or lab director. The inspector requested to review the performance of additional twice-annual verifications from July 2020 up to the date of survey. The additional documents were not available for review. 4. An exit interview with the general supervisor and owner of the lab on 10/08/21 at approximately 4 PM confirmed the findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), proficiency testing (PT) records and interviews, the lab failed to follow the established policy for the review of two of two urine toxicology PT events at the date of survey on 10/08/21. Findings include: 1. The lab participates with the College of American Pathologists (CAP) urine toxicology Drug Monitoring for Pain Management (DMPM) for 44 analytes (refer to D5217 finding #2). 2. Review of the P&P revealed the following: "SOP for Proficiency Testing" (signed by the lab director 02/01/20), It is a Laboratory Policy to handle PT samples, to the greatest extent possible, as donor samples. In order to ensure the highest quality testing: 1. Promptly review the PT scores. 2. Recognize any failures. 3. Identify the source or reason for failure(s). 4. Take immediate steps to resolve the issue(s). PT failures must be addressed promptly and thoroughly to resolve the problem that caused the failure. The laboratory should always be mindful that: 1. PT results are reported to regulatory agencies for the purpose of monitoring performance. 2. PT failures may indicate a problem with patient test results. Re-analysis of patient specimens that were tested concurrently with the failed PT specimen(s) may be necessary to ensure that patient quality of care has not been compromised. 3. Prevention of additional PT failures is necessary to achieve laboratory success." 3. Review of the available documents from the CAP DMPM-A and B events and interview with the general supervisor and lab owner on 10/08/21 at approximately 10:30 AM revealed the lab received, tested and faxed results on 03/31 /21 (Event A) and 08/31/21 (Event B). The original evaluations from CAP provided the code "[40] Results for this test kit were not received" for both events. The CAP DMPM-A 2021 revised evaluation on 10/08/21 revealed the unacceptable results for Hydromorphone, nordiazepam, morphine and pregabalin. No revision evaluation was available for CAP DMPM-B 2021 at the date of survey. At the date of survey, neither evaluation had been reviewed by the general supervisor, technical supervisor or lab director. 4. An exit interview with the general supervisor and owner of the lab on 10 /08/21 at approximately 4 PM confirmed the findings.

D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), proficiency testing (PT) records and interviews, the lab director failed to follow the established policy for the review of two of two urine toxicology PT events (Refer to D5221) and ensure twice annual verification of toxicology analytes (Refer to D5217) at the date of survey on 10/08/21.