Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2015110	(X3) Date Survey Completed 02/23/2023
Name of Provider or Supplier Kokomo Pain Management, Llc	**Street Address, City, State** 18077 River Rd Ste 200, Noblesville, 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
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to provide qualification documentation to ensure one (Trainer) of two personnel performing responsibilities of a Technical Consultant (TC) was qualified from October 2022 to February 2023 (refer to D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the

technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on document review and interview, the laboratory failed to provide qualification documentation to ensure one (Trainer) of two personnel performing responsibilities of a Technical Consultant (TC) was qualified from October 2022 to February 2023. Findings Include: 1. Review of the Laboratory Personnel Report CMS 209, SP-1 is listed as a testing person for moderate complexity testing. SP-4 (former testing person) and Trainer are not listed on the CMS 209. 2. Review of personnel file binders SP-1 and SP-4 indicated they were testing personnel. SP-4 no longer works for the facility as of 2023. Competency for both SP-1 and SP-4 prior to testing patients on the analyzer, Indiko Plus (SN# 864000090385), Thermo Fisher was performed by Trainer. SP-1 has a "Proficiency Evaluation LIS" for the Indiko Plus completed on 12/6/2022. SP-4 has a "Proficiency Evaluation LIS" for the Indiko plus completed on 10/12/2022. These documents were not signed by SP-3 who was listed on the CMS 209 at the technical consultant. 3. Review of training documents for SP-1and SP-4 (Testing Personnel), titled: Indiko Training Checklist, Understanding Reagents, Understanding Calibrators, Proficiency Evaluation LIS and Proficiency Evaluation Indiko identifies Trainer 1 (not listed of the CMS 209) as the person(s) providing the training on 10/12/22 and 12/06/22 for analyzer, Indiko Plus (SN# 864000090385), Thermo Fisher. The training documents were not signed by the laboratory director, or the Technical Consultant listed on the CMS 209. 4. Review of document "LIS WORKSHEET Laboratory Information System Accuracy Review" for the Indiko lists Trainer as the person who reviewed the Laboratory Information System (LIS) implementation on 10/21/2022. 5. On 02/15/23 at 4:05pm, during a phone interview, SP-3 (Technical Consultant) was asked to provide documentation to verify who performed the "Performance Specification" for the analyzer, Indiko Plus (SN# 864000090385) since the original document did not list a signature or name under "All testing for this verification were performed by". 6. On 2/15/2023 at 4: 09pm, an email for document titled "Verification Summary for the Demonstration of Performance Specifications, Qualitative Immunoassay Analysis" was received from SP-3 (Technical Consultant). The document listed the testing personnel (SP-4), not Technical Consultant (SP-3) as the person for "All testing for this verification were performed by", dated 10/19/2022 and signed by the Laboratory Director on 10/20 /2023. The other person listed as completing the report was Trainer. 7. Upon request for qualification documentation for Trainer, on 2/15/2023 at 4:09 pm, SP-3 (Technical

	Consultant) stated, "Trainer assisted (not performed)" verification process for the Indiko Plus. 8. On 02/23/23 at 8:26am, an email was sent to the laboratory in attempt to verify the education of Trainer to qualify the person as a technical consultant. A reply sent at 11:23am from SP-3 (Technical Consultant) did not provide the qualification documentation.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to provide qualification documentation during the course of inspection for one (Trainer) of two personnel performing responsibilities of a Technical Consultant (TC) to verify qualifications from October 2022 to February 2023. Findings include: 1. Review of the Laboratory Personnel Report CMS 209, SP-1 is listed as a testing person for moderate complexity testing. SP-4 (former testing person) and Trainer are not listed on the CMS 209. 2. Review of personnel file binders of SP-1 and SP-4 indicated they were testing personnel. SP-4 no longer works for the facility as of 2023. Competency for both SP-1 and SP-4 prior to testing patients on the analyzer, Indiko Plus (SN# 864000090385), Thermo Fisher was performed by Trainer. SP-1 had a "Proficiency Evaluation LIS" for the Indiko Plus completed on 12/6/2022. SP-4 has a "Proficiency Evaluation LIS" for the Indiko plus completed on 10/12/2022. These documents were not signed by SP-3 who was listed on the CMS 209 as the technical consultant. 3. Review of training documents for SP-1and SP-4 (Testing Personnel), titled: Indiko Training Checklist, Understanding Reagents, Understanding Calibrators, Proficiency Evaluation LIS and Proficiency Evaluation Indiko identifies Trainer (not listed of the CMS 209) as the person(s) providing the training on 10/12/22 and 12/06/22 for analyzer, Indiko Plus (SN# 864000090385), Thermo Fisher. The training documents were not signed by the laboratory director, or the Technical Consultant listed on the CMS 209. 4. Review of document "LIS WORKSHEET Laboratory Information System Accuracy Review" for the Indiko lists Trainer as the person who reviewed the Laboratory Information System (LIS) implementation on 10/21/2022. 5. On 02/15/23 at 4:05pm, during a phone interview, SP-3 (Technical Consultant) was asked to provide documentation to verify who performed the "Performance Specification" for the analyzer, Indiko Plus (SN# 864000090385) since the original document did not

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