

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0901418	(X3) Date Survey Completed 05/15/2023
Name of Provider or Supplier Dplm At Iu Health - Methodist Medical Plaza South	Street Address, City, State 8830 S Meridian, 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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure two (SP-4 and Sp-7) of two personnel performing the duties of a technical consultant (TC) were qualified (Refer to D6035).</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(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</p>

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 record review and interview, the laboratory director failed to ensure two (SP-4 and SP-7) of two personnel performing the duties of a technical consultant (TC) met qualification requirements. Findings Included: 1. Review of "Laboratory Personnel Report (CLIA)", signed by the laboratory director on 5/10/2023 indicated the following: a) SP-1 is a Technical Consultant. b) SP-7 is a testing person. 2. Review of education for SP-4 (Technical Consultant) revealed a copy of Bachelor of Science (B. S.) Degree that did not specify a major. Transcripts provided for the B.S identified the major as Health Arts with a transfer of 80 credits from associate degree in medical laboratory technology, with no science courses (in chemical, physical, or biological) taken during the completion of the B.S; it was determined based on the information provided that SP-4 did not qualify as a technical consultant. 3. Review of education for SP-7 (Testing Person) revealed they had a high school diploma and did not qualify as a technical consultant (TC). 4. Review of document titled, "Beckman Coulter Unicel DxH 600, Competency Module and Director Observation" revealed competency evaluation for Testing Personnel (SP-5) on analyzer: Unicel DxH 600 (S/N: AW49326, System ID: 8955629) was conducted by Technical Consultant (SP-4) specified as both the "trainer and trainee". Further review indicated; another Testing Personnel (SP-7) also assisted in competency training on 5/20/2022. 5. Review of document titled, "Unicel DxH 600, Competency Module and Director Observation" revealed competency evaluation for Testing Personnel (SP-6) and Testing Personnel (SP-8) on analyzer: Unicel DxH 600 (S/N: AW49326, System ID: 8955629) was conducted by Technical Consultant (SP-4) on 6/3/2022, 9/7/2022, and 1/4/2023. Further review indicated; another Testing Personnel (SP-7) also assisted in competency training on 6/3/2023, 9/7/2022 and 1/4/2023. 6. Review of "Testing Personnel Responsibilities Delegated by the Laboratory Director Moderate Complexity Laboratory" for Testing Personnel (SP-7), signed by the laboratory director and Testing Personnel (SP-7) on 3/22/2018 indicated, the job responsibilities "(1) perform only testing for which the individual is authorized as indicated by the successful completed and approved training records." 7. Review of document titled, "Competency Assessment Form Technical Consultant" revealed competency evaluation for Technical Consultant (SP-4) on analyzer: Unicel DxH 600 (S/N: AW49326, System ID: 8955629) was conducted by the laboratory director (SP-1) on 5/10/2023. Assessment statement signed by the laboratory director acknowledged, "individual meets the expectations of all criteria for technical consultant ...and is

authorized to perform signed duties and responsibilities". 8. Review of policy titled, "Job Delegation (CLIA and Safety Representative)" signed by the laboratory director on 3/27/23. Under IV. Definitions, CLIA DEFINED PERSONNEL TITLES AND JOB RESPONSIBILITIES (CLIA JOB DESCRIPTION) for Technical Consultant: (Moderate Complexity Testing), page 6., number 10, states, "The Technical Consultant is responsible for evaluating the competency of the personnel performing moderate complexity". Further review of the policy for subtitle: Testing Personnel: High and Moderate Complexity on page 6., confirms testing personnel "once trained, can complete competency observation for waived testing", not for non-waived (Moderate Complexity Testing). 9. Review of policy titled, "Job Delegation (CLIA and Safety Representative)" signed by the laboratory director on 3/27/2023. Under V. Policy Statements, B. Technical Consultant, 2. Moderate Complexity, 3. states, "bachelor's degree in chemical, physical; biological or clinical laboratory science with at least 2 years of training" is the requirements for Technical Consultant (TC). 10. On 5/15/2023 at 9:25am, during an interview with SP-4 (Technical Consultant), SP-4 was asked to provide any additional education documents that specifies upper-level sciences courses were taken as part of the Bachelor Science (BS), Major: Health Arts. Sp-4 did not provide any additional documentation.