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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 15D2053061 | (X3) Date Survey Completed 06/01/2022 |
| Name of Provider or Supplier Nephrology Assoc Of Northern Ind | Street Address, City, State 7836 W Jefferson Blvd Ste 101, Fort Wayne, 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 |
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| D2016 | <p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to successfully participate in the American Association of Bioanalysts (AAB) proficiency testing (PT) program for chloride (Cl). The laboratory had three consecutive unsatisfactory testing events (Events 1, 2, and 3, 2020). (Refer to D2096.)</p> |
| D2096 | <p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p> |

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory failed to achieve a satisfactory proficiency testing (PT) score of 80% or higher for chloride (Cl) testing during three out of three consecutive PT events (Event 1, 2020, Event 2, 2020, and Event 3, 2020), resulting in unsatisfactory performance. Findings include: 1. Review of "CASPER Report 0155D" indicated the laboratory received a score of 60% during PT testing event 1, 2020, 20% during event 2, 2020, and 40% during event 3, 2020 for Cl testing through the American Association of Bioanalysts (AAB) PT program. 2. On 06/01/2022 at 10:23 am, SP1, laboratory director, acknowledged that the laboratory received three consecutive failing PT scores for Cl in 2020. 3. Annual test volume for chloride is 3,442.

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 record review and interview, the laboratory failed to ensure two of two personnel (SP2 and SP3) performing the duties of a technical consultant (TC) were qualified personnel (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 record review and interview, the laboratory failed to ensure two of two (SP2 and SP3) personnel performing the duties of a technical consultant (TC) meet qualification requirements. Findings include: 1. Review of SP2's education documentation indicated that they received an associate of science in medical laboratory technology. 2. Review of SP3's education documentation indicated they were a high school graduate. 3. Review of the 2021 and 2022 annual competency assessment documentation for SP3, completed March 30, 2021 and April 15, 2022, indicated that SP2 performed the competency assessment. 4. Review of the 2021 and 2022 annual competency assessment documentation for SP2, completed March 30, 2021 and April 15, 2022, indicated that SP3 performed the competency assessment. 5. On 06/01/2022 at 1:45 pm, SP2, testing person/ practice manager, acknowledged that they and SP3, testing person, had been performing each other's competency assessments.