| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 23D2242011 | 08/15/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ak Diagnostic Laboratory Llc | 35540 W Michigan Avenue, Wayne, MI | |

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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| **D0000** | . The purpose of this unannounced survey was for a follow-up to the 5/15/23 initial survey. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003). |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>. Based on record review and interviews, the Laboratory Director was not qualified to manage and direct performance of high complexity testing (refer to D6078), failed to ensure laboratory personnel followed procedures for specimen rejection for 18 of 18 female specimens reviewed for Prostate Specific Antigen (PSA) testing (refer to D6087 A), failed to ensure laboratory personnel followed its Prostate Specific Antigen (PSA) test procedure for 18 of 18 female specimens with Prostate Specific Antigen (PSA) testing reviewed (refer to D6087 B), failed to ensure the Clinical Consultant provided consultation regarding the appropriateness of ordering Prostate Specific Antigen (PSA) testing on female patient specimens (refer to D6101 A), and failed to ensure testing personnel followed the laboratory's Prostate Specific Antigen (PSA) test procedure for 18 of 18 female specimens with Prostate Specific Antigen (PSA) testing (refer to D6101 B). |
| **D6078** | LABORATORY DIRECTOR QUALIFICATIONS<br>CFR(s): 493.1443<br><br>The laboratory director must be qualified to manage and direct the laboratory |

personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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) Be a doctor of medicine, a 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Consultant, the Laboratory Director was not qualified to manage and direct performance of high complexity testing from 8/1/23 to 8/15/23. Findings include: 1. A review of the laboratory's patient test requests and test reports from 7/28/23 to 8/14/23 revealed the following 18 patients were indicated as female on the test request and had PSA testing reported: a. Patient 56855 had PSA testing and results reported on 8/1/23. b. Patient 56856 had PSA testing and results reported on 8/1/23. c. Patient 56905 had PSA testing and results reported on 8/3/23. d. Patient 56956 had PSA testing and results reported on 8/3/23. e. Patient 56959 had PSA testing and results reported on 8/3/23. f. Patient 57101 had PSA testing and results reported on 8/14/23. g. Patient 57143 had PSA testing and results reported on 8/14/23. h. Patient 57102 had PSA testing and results reported on 8/14/23. i. Patient 57141 had PSA testing and results reported on 8/14/23. j. Patient 57144 had PSA testing and results reported on 8/14/23. k. Patient 57145 had PSA testing and results reported on 8/14/23. l. Patient 57200 had PSA testing and results reported on 8/14/23. m. Patient 57201 had PSA testing and results reported on 8/14/23. n. Patient 57203 had PSA testing and results reported on 8/14/23. o. Patient 57205 had PSA testing and results reported on 8/14/23. p. Patient 57222 had PSA testing and results reported on 8/14/23. q. Patient 57221 had PSA testing and results reported on 8/14/23. r. Patient 57254 had PSA testing and results reported on 8/14/23. 2. A review of the laboratory's "Hybritech Prostate Specific Antigen (PSA) Test

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| | Procedure" approved by the Laboratory Director on 6/30/23 revealed a section titled "Intended Use" stating, "This device is indicated for the measurement of serum PSA in conjunction with digital rectal examination (DRE) as an aid in the detection of prostate cancer in men aged 50 years or older. Prostate biopsy is required for the diagnosis of cancer. This device is further indicated for the serial measurement of PSA to aid in the prognosis and management of patients with prostate cancer" and revealed no indication of this assay to be used on patients indicated as female. This test system defaulted to high complexity testing. 3. A review of the Laboratory Director's qualifications revealed a lack of documentation showing the high complexity Laboratory Director qualification requirements were met. 4. An interview on 8/15/23 at 10:48 am with Technical Consultant confirmed the laboratory had performed PSA testing on female patient specimens against laboratory procedure and testing would be considered high complexity, making the Laboratory Director unqualified to serve. |
| **D6087** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(iii)<br><br>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>. A. Based on record review and interview, the Laboratory Director failed to ensure laboratory personnel followed procedures for specimen rejection for 18 of 18 female specimens reviewed for Prostate Specific Antigen (PSA) testing. Refer to D5311. B. Based on record review and interview, the Laboratory Director failed to ensure laboratory personnel followed its Prostate Specific Antigen (PSA) test procedure for 18 of 18 female specimens with Prostate Specific Antigen (PSA) testing reviewed. Refer to D5401. |
| **D6101** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(11)<br><br>The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.<br><br>This STANDARD is not met as evidenced by:<br>. A. Based on record review and interview, the Laboratory Director failed to ensure the Clinical Consultant provided consultation regarding the appropriateness of ordering Prostate Specific Antigen (PSA) testing on female patient specimens. Refer to D6136. B. Based on record review and interview, the Laboratory Director failed to ensure testing personnel followed the laboratory's Prostate Specific Antigen (PSA) test procedure for 18 female specimens with Prostate Specific Antigen (PSA) testing. Refer to D6175. |
| **D6135** | CLINICAL CONSULTANT QUALIFICATIONS<br>CFR(s): 493.1455<br><br>The clinical consultant must be qualified to consult with and render opinions to the |

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| | laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview, the Clinical Consultant failed to provide consultation regarding the appropriateness of ordering Prostate Specific Antigen (PSA) testing on female patient specimens. Refer to D6136. |
| **D6136** | CLINICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1457<br><br>The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Technical Consultant, the Clinical Consultant failed to provide consultation regarding the appropriateness of ordering Prostate Specific Antigen (PSA) testing on female patient specimens for 1 of 1 client the laboratory serves. Findings include: 1. A review of the laboratory's test requests revealed 18 female patients had PSA testing ordered between 7/28/23 to 8/11/23 from the laboratory's one client: a. Patient 56855 had PSA testing ordered on 7/28/23 and results reported on 8/1/23. b. Patient 56856 had PSA testing ordered on 7/28/23 and results reported on 8/1/23. c. Patient 56905 had PSA testing ordered on 7/31/23 and results reported on 8/3/23. d. Patient 56956 had PSA testing ordered on 8/1/23 and results reported on 8/3/23. e. Patient 56959 had PSA testing ordered on 8/1/23 and results reported on 8/3/23. f. Patient 57101 had PSA testing ordered on 8/7/23 and results reported on 8/14/23. g. Patient 57143 had PSA testing ordered on 8/7/23 and results reported on 8/14/23. h. Patient 57102 had PSA testing ordered on 8/7/23 and results reported on 8/14/23. i. Patient 57141 had PSA testing ordered on 8/8/23 and results reported on 8/14/23. j. Patient 57144 had PSA testing ordered on 8/8/23 and results reported on 8/14/23. k. Patient 57145 had PSA testing ordered on 8/8/23 and results reported on 8/14/23. l. Patient 57200 had PSA testing ordered on 8/9/23 and results reported on 8/14/23. m. Patient 57201 had PSA testing ordered on 8/9/23 and results reported on 8/14/23. n. Patient 57203 had PSA testing ordered on 8/9/23 and results reported on 8/14/23. o. Patient 57205 had PSA testing ordered on 8/9/23 and results reported on 8/14/23. p. Patient 57222 had PSA testing ordered on 8/11/23 and results reported on 8/14/23. q. Patient 57221 had PSA testing ordered on 8/11/23 and results reported on 8/14/23. r. Patient 57254 had PSA testing ordered on 8/11/23 and results reported on 8/14/23. 2. An interview on 8/16/23 at 8:58 am with the Technical Consultant confirmed there was a lack of documentation of consultation with the Clinical Consultant regarding the appropriateness of PSA testing in female patients for the client requesting testing. |
| **D6168** | TESTING PERSONNEL<br>CFR(s): 493.1487<br><br>The laboratory has a sufficient number of individuals who meet the qualification |

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| | requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>. Based on record review and interview, testing personnel failed to follow its Prostate Specific Antigen (PSA) test procedure for 18 of 18 female specimens with Prostate Specific Antigen (PSA) testing. Refer to D6175. |
| **D6175** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1495(b)(1)<br><br>Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview, testing personnel failed to follow its Prostate Specific Antigen (PSA) test procedure for 18 of 18 female specimens with Prostate Specific Antigen (PSA) testing. Refer to D5401. |