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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D0887857 | (X3) Date Survey Completed 08/12/2024 |
| Name of Provider or Supplier Physicians Immunodiagnostic | Street Address, City, State 512 S Verdugo Dr, Burbank, CA | |
| 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 | A proficiency testing desk review survey was performed on 8/12/2024, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. |
| 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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D and AAB-Medical Laboratory Evaluation / College of American Pathologists/EXCEL) records (2023-2, 2023-3) and (2024-1), the laboratory failed to</p> |

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| | <p>successfully participate in a proficiency testing program approved by HHS for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA, the laboratory failed to successfully participate in the subspecialty of Parasitology, General Immunology analyte C4, and Routine Chemistry analyte BUN resulting in unsuccessful performances. Refer to D2.</p> |
| <p>D2055</p> | <p>PARASITOLOGY CFR(s): 493.829(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and AAB-Medical Laboratory Evaluation / College of American Pathologists/EXCEL) reports, the laboratory failed to achieve satisfactory performance for two of three events proficiency events in 2023 and 2024 for Parasitology. The finding include 1. The laboratory received the following scores: 0% on the 2023 Parasitology third event 75% on the 2024 Parasitology first event 2. A review of the 2023 and 2024 proficiency Testing scores from AAB and CAP confirmed the above findings.</p> |
| <p>D2085</p> | <p>GENERAL IMMUNOLOGY CFR(s): 493.837(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and AAB-Medical Laboratory Evaluation / College of American Pathologists/EXCEL) reports, the laboratory failed to achieve satisfactory performance for two of three events proficiency events in 2023 and 2024 for C4. The finding include 1. The laboratory received the following scores: 0% on the 2023 C4 third event 60% on the 2024 C4 first event 2. A review of the 2023 and 2024 proficiency Testing scores from AAB and CAP confirmed the above findings.</p> |
| <p>D2097</p> | <p>ROUTINE CHEMISTRY CFR(s): 493.841(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and AAB-Medical</p> |

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| | <p>Laboratory Evaluation / College of American Pathologists/EXCEL) reports, the laboratory failed to achieve satisfactory performance for two of three events proficiency events in 2023 and 2024 for BUN. The finding include 1. The laboratory received the following scores: 0% on the 2023 BUN third event 75% on the 2024 BUN second event 2. A review of the 2023 and 2024 proficiency Testing scores from AAB and CAP confirmed the above findings.</p> |
| <p>D6000</p> | <p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 155 report API records for 2023-2, 2023-3 and 2024-1 events, the laboratory director failed to provide overall management and a direction of the laboratory services. Refer to D6016.</p> |
| <p>D6016</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 155 report, AAB & CAPI records for 2023-2 and 2024-1 events, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2055, D2085, and D2097..</p> |