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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D0658083 | (X3) Date Survey Completed 04/07/2025 |
| Name of Provider or Supplier Lab Clinico Y De Referencia Del Este | Street Address, City, State 303 General Valero Avenue, Fajardo, PR | |
| 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 Test Desk Review off site survey was performed on April 7, 2025 to Laboratorio Clinico Referencia Del Este, the laboratory was found out of compliance with the following conditions: 42 CFR 493.803 Proficiency Testing, Successful Participation 42 CFR 493.1403 Laboratory Director, Moderate complexity |
| 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 Puerto Rico Proficiency Testing scores (year 2024) and CASPER Report 0155D scores, it was determined that the laboratory obtained a unsuccessful participation in a Proficiency Testing Program for Ova/ & Parasite (presence or absent) tests. Refer D2055.</p> |

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| <p>D2055</p> | <p>PARASITOLOGY CFR(s): 493.829(e)</p> <p>(e) 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 review of Puerto Rico Proficiency Testing scores (year 2024) and CASPER Report 0155D scores, it was determined that the laboratory obtained an initial unsuccessful performance in two out of three consecutive testing events for Ova & Parasite tests. The finding includes: 1. The Puerto Rico Proficiency and Casper Report 0155D scores, showed that the laboratory obtained the following unsuccessful scores: Analyte: Ova & Parasite (presence or absent) a. First testing event year 2024 - 60% b. Third testing event year 2024 - 60%</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 review of Puerto Rico proficiency testing scores (year 2024) and CASPER Report 0155D scores, its was determined that the laboratory director failed to ensure the laboratory's successful participation in a Proficiency Testing Program for Ova & Parasite (presence or absent) tests. Refer to D6016.</p> |
| <p>D6016</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) 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 Puerto Rico proficiency testing scores (year 2024) and CASPER Report 0155D scores, it was determined that the laboratory director did not ensure that the laboratory had a satisfactory participation for Ova & Parasite (presence or absence) tests during the first testing event of the year 2024 and third testing event of the year 2024. Refer to D2055.</p> |