

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D1012009	<b>(X3) Date Survey Completed</b>  03/27/2023
<b>Name of Provider or Supplier</b>  Lewis Family Care	<b>Street Address, City, State</b>  6628 Us 60, Ashland, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Based on desk review of proficiency testing (PT) from 2022 through 2023 the laboratory failed to meet the following conditions resulting in a noninitial unsuccessful PT performance: D2016 - SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) D6000 - MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403
<b>D2016</b>	<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 a desk review of proficiency testing records, the laboratory failed to 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</p>

	<p>CLIA. The laboratory failed to successfully participate in the specialty of Routine Chemistry and the subspecialty of Endocrinology. (Refer to D2096, D2107, D2108)</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in 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 a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 Individual Laboratory Report and American Proficiency Institute 2022 records (1st, 2nd and 3rd events), the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two of three events in the specialty of Routine Chemistry for the analyte Creatinine and two consecutive testing events for the analyte Total Bilirubin (Bili, Total). The findings include: 1. Review of the Casper -0155 report revealed the following: Routine Chemistry 2022- 1st Event Laboratory received an unsatisfactory score of 20% for Creatinine Routine Chemistry 2022- 3rd Event Laboratory received an unsatisfactory score of 0% for Creatinine. Routine Chemistry 2022- 2nd Event Laboratory received an unsatisfactory score of 40% for BILI, Total Routine Chemistry 2022- 3rd Event Laboratory received an unsatisfactory score of 0% for BILI, Total 2. A proficiency testing desk review from API 2022 proficiency testing records confirmed the above findings.</p>
<b>D2107</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in 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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) testing records from 2022 and 2023, the laboratory failed to achieve a testing event score of satisfactory performance (80% or greater) for two consecutive testing events for the analyte Thyroid Stimulating Hormone (TSH) in the subspecialty in Endocrinology. The findings include: 1. Review of the Casper -0155 report revealed the following: Endocrinology 2022- 3rd Event Laboratory received an unsatisfactory score of 0% for TSH Endocrinology 2023- 1st Event Laboratory received an unsatisfactory score of 40% for TSH. 2. A proficiency testing desk review from API 2022 and 2023 proficiency testing records confirmed the above findings.</p>
<b>D2108</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) report 155 Individual Laboratory Profile, American Proficiency Institute (API) testing records from 2022 and 2023, the laboratory failed to achieve an overall testing even score of satisfactory performance (80% or greater) for two consecutive testing events in the subspecialty Endocrinology resulting in unsuccessful performance. The findings include: 1. Review of the Casper -0155 report revealed the following: Endocrinology 2022- 3rd Event Laboratory received an overall unsatisfactory score of 0% FOR ENDOCRINOLOGY Endocrinology 2023- 1st Event Laboratory received an overall unsatisfactory score of 70% FOR ENDOCRINOLOGY 2. A proficiency testing desk review from API 2022 and 2023 proficiency testing records confirmed the above findings.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b>  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 desk review of laboratory proficiency testing performance, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.</p>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  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 desk review of proficiency testing results, it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2096, D2107, and D2108.</p>