

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0489140	<b>(X3) Date Survey Completed</b> 06/11/2025
<b>Name of Provider or Supplier</b> Family Health Center Of Ozona	<b>Street Address, City, State</b> 102 North Ave H, Ozona, TX	
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 a proficiency testing desk review survey performed on June 11, 2025, the laboratory was found to be out of compliance based on the following <b>CONDITION LEVEL DEFICIENCIES</b> : D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 <b>CONDITION</b> is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the laboratory's College of American Pathologists (CAP) proficiency testing (PT) reports, the laboratory failed to</p>

	<p>achieve satisfactory performance in two consecutive events in 2025 for the analyte of hematocrit (HCT) (refer to D2130) resulting in an initial unsuccessful performance.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte in two consecutive 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 the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and College of American Pathologists (CAP) proficiency testing (PT) reports, the laboratory failed to achieve satisfactory performance in two consecutive testing events in 2025 for the analyte of hematocrit (HCT) resulting in an initial unsuccessful performance. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile report, the laboratory received the following unsatisfactory scores for HCT in two consecutive testing events: 2025 CAP 1st event 20% 2025 CAP 2nd event 40% 2. Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing reports, the laboratory received the following unsatisfactory scores for hematocrit in two consecutive events: 2025 CAP 1st event 20% 2025 CAP 2nd event 40%</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 the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the laboratory's College of American Pathologists (CAP) proficiency testing reports, the laboratory director failed to provide overall management and direction of laboratory services when the laboratory failed the analyte of hematocrit for the 1st and 2nd testing events in 2025. Refer to D6016.</p>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the laboratory's College of American Pathologists (CAP) proficiency testing reports, the laboratory director failed</p>

to ensure successful participation in an HHS approved proficiency testing program for the analyte of hematocrit (HCT) (refer to D2130) for two consecutive events in 2025, resulting in an initial unsuccessful performance.