

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2141778	(X3) Date Survey Completed 03/25/2024
Name of Provider or Supplier Ronald C Fagan Md Pc	Street Address, City, State 4230 Hempstead Turnpike, Suite 109, Bethpage, NY	
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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, lack of corrective action records, and interview with the testing person (TP), corrective action was not performed for UniCel DXI 600 analyzer QC materials that did not perform within established operating specifications. FINDINGS: 1. hFSH, hLH, PRL Level 1 Lot 40420 and Level 3 Lot 40423 calibrations were flagged on November 20, 2023. 2. No documentation of subsequent corrective action performance. 3. Approximately 10,000 patients were tested and results reported. 4. Clinical consultant (CC) confirmed findings on March 25, 2024, at approximately 11:30 A.M. Refer to 6022.</p>
D6022	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:

Based on a review of quality assessment (QA) and QC records, as well as interview with the technical consultant (TC), the laboratory director (LD) failed to comply with current, approved UniCel DXI 600 QA and QC protocols to assure quality of laboratory services. FINDINGS: 1. TC confirmed the findings on March 25, 2024, at approximately 11:30 A.M. Refer to: D5783.